

COMPARING MINDFULNESS-BASED STRESS REDUCTION WITH THE
HEALTH ENHANCEMENT PROGRAM IN THE TREATMENT OF URGE
URINARY INCONTINENCE IN OLDER ADULT WOMEN: A PILOT
FEASIBILITY AND RANDOMIZED CONTROLLED TRIAL

by

Katarina Friberg Felsted

A dissertation submitted to the faculty of
The University of Utah
in partial fulfillment of the requirements for the degree of

Doctor of Philosophy

College of Nursing

The University of Utah

May 2018

Copyright © Katarina Friberg Felsted 2018

All Rights Reserved

The University of Utah Graduate School

STATEMENT OF DISSERTATION APPROVAL

The dissertation of Katarina Friberg Felsted
has been approved by the following supervisory committee members:

<u>Katherine P. Supiano</u>	, Chair	<u>12/7/2017</u> Date Approved
<u>Michael Caserta</u>	, Member	<u>12/7/2017</u> Date Approved
<u>Angela Deneris</u>	, Member	<u>12/7/2017</u> Date Approved
<u>Jia-Wen Guo</u>	, Member	<u>12/7/2017</u> Date Approved
<u>Paul Thielking</u>	, Member	<u>12/7/2017</u> Date Approved

and by Patricia Morton, Chair/Dean of
the Department/College/School of Nursing

and by David B. Kieda, Dean of The Graduate School.

ABSTRACT

Urge urinary incontinence (UUI) disproportionately affects older women and adversely affects health related quality of life. Current medications have dangerous side effects in the older adult population, including falls and confusion. Older adult women with UUI are not sufficiently treated with current practices.

There were three aims to this research. 1) To determine the research feasibility of a randomized controlled trial (RCT) comparing mindfulness-based stress reduction (MBSR) and the health enhancement program (HEP) in older adult women presenting with UUI, measured by recruitment, retention, and treatment fidelity. 2) To determine the intervention feasibility of an RCT comparing MBSR and HEP in older adult women presenting with UUI, measured by acceptability, tolerability, and treatment adherence. Finally, there was an exploratory aim 3) to evaluate short term preliminary efficacy of MBSR for treatment of UUI in older adult women, in comparison to HEP, measured by symptom severity, symptom bother, perceived stress, perceived self-efficacy, and the trajectory of change.

Twenty-five postmenopausal women were recruited. Interested women were screened and subsequently enrolled, then randomized into one of two therapeutic (nonsurgical, nonpharmacological) approaches. They completed an 8-week intervention, remaining blinded to condition.

A wide scope of feasibility determinants were examined—research: recruitment,

retention, and treatment fidelity; intervention: acceptability, tolerability, and treatment adherence. All were successfully met. Additionally, severity, bother, perceived stress, perceived self-efficacy, and the rate and trajectory of change were examined in the exploratory aim. Participants saw significant improvement in all five areas.

This study supports prior research suggesting potential efficacy of MBSR and elements of HEP in treating UUI in older adult women. Study findings contribute to our understanding of the complex condition of UUI in an older, more vulnerable and underrepresented population.

These study findings support the merit of future research in larger scale and/or multisite trials. In addition, development and evaluation of a combined MBSR and HEP therapy to address UUI in older adult women is hypothesized to produce higher efficacy across study domains, and merits further study.

The longer I live, the more beautiful life becomes.
– Frank Lloyd Wright

TABLE OF CONTENTS

ABSTRACT.....	iii
LIST OF TABLES	ix
LIST OF FIGURES	x
ACKNOWLEDGMENTS	xi
Chapters	
1. INTRODUCTION	1
1.1 Urinary Incontinence	2
1.2 Problem Statement	7
1.3 Purpose of the Study	7
1.4 Organization of Dissertation	7
1.5 References.....	8
2. LITERATURE REVIEW	12
2.1 Urge Urinary Incontinence	13
2.2 Theoretical Framework	22
2.3 Mindfulness-Based Stress Reduction	26
2.4 References.....	31
3. USING MINDFULNESS APPROACHES TO TREAT URGE URINARY INCONTINENCE IN OLDER ADULT WOMEN: A LITERATURE REVIEW	43
3.1 Abstract	44
3.2 Introduction.....	45
3.3 Background	45
3.4 Methods.....	46
3.5 Results.....	50
3.6 Discussion	54
3.7 Conclusion	54
3.8 References.....	59
4. METHODS	62
4.1 Design Overview	63

4.2 Intervention Description	64
4.3 Participants.....	67
4.4 Recruitment.....	71
4.5 Procedure	73
4.6 Setting	78
4.7 Measures	78
4.8 Analytic Plan.....	88
4.9 Effect Sizes and Power Analysis	95
4.10 Study Challenges and Limitations	95
4.11 References.....	97
4.12 Supplemental Information	106
 5. DESIGNING RIGOROUS METHODS IN INTEGRATIVE RESEARCH: COMPARING MINDFULNESS-BASED STRESS REDUCTION WITH THE HEALTH ENHANCEMENT PROGRAM IN THE TREATMENT OF URGE URINARY INCONTINENCE IN OLDER ADULT WOMEN: A PILOT FEASIBILITY AND RANDOMIZED CONTROLLED TRIAL (SHUW)	 135
5.1 Abstract.....	136
5.2 Background.....	136
5.3 Methods.....	138
5.4 Discussion	150
5.5 Conclusion	151
5.6 Conflicts of Interest.....	152
5.7 Acknowledgments.....	152
5.8 Trial Registry	152
5.9 References.....	154
 6. A FEASIBILITY RANDOMIZED CONTROLLED TRIAL: COMPARING MINDFULNESS-BASED STRESS REDUCTION WITH THE HEALTH ENHANCEMENT PROGRAM IN THE TREATMENT OF URGE URINARY INCONTINENCE IN OLDER ADULT WOMEN	 157
6.1 Abstract.....	158
6.2 Introduction.....	159
6.3 Materials and Methods.....	160
6.4 Framework	161
6.5 Results and Discussion	162
6.6 Conclusion	171
6.7 References.....	174
 7. RESULTS	 177
7.1 Demographics	179
7.2 Outcome Measures.....	183
7.3 Key Findings.....	184
7.4 Acknowledgments.....	194

7.5 References.....	195
7.6 Supplementary Information	197
8. DISCUSSION	208
8.1 Implications.....	212
8.2 Conclusion	213
8.3 References.....	215

LIST OF TABLES

Tables

1 Study Characteristics	57
2 Outcome Measures.....	58
3 Rationale for Choosing HEP Comparison Condition.	106
4 Curricula Comparison of Mindfulness-Based Stress Reduction and Health Enhancement Program	108
5 Study Measures Overview	124
6 Outcome and Process Measures.....	197
7 Characteristics of Overall Sample for Continuous Items ($N = 25$).....	198
8 Characteristics of Overall Sample for Categorical Items ($N = 25$).....	199
9 Fisher's Exact Test to Examine Differences in Categorical Baseline Characteristics Between MBSR and HEP Conditions ($n = 13$; $n = 12$)	200
10 Mann-Whitney U Tests to Test for Differences in Baseline Characteristics Between MBSR Versus HEP Conditions ($n = 13$; $n = 12$).....	201
11 Analysis of the Assumptions of Normality on Outcome Measures.....	202
12 Analysis of the Effect of MBSR Versus HEP on Outcome Measures	203
13 Within Group Results Using Paired t tests and Wilcoxon Signed Ranks Test (MBSR condition)	204
14 Within Group Results Using Paired t tests and Wilcoxon Signed Ranks Test (HEP condition)	204
15 Effect Size and Power Analysis of Differences in Outcome Measures Between MBSR and HEP Using Independent Samples t test.....	206
16 Effect Sizes and Power Analysis of Differences in Outcome Measures Between MBSR and HEP using Mann-Whitney U Tests.....	207

LIST OF FIGURES

Figures

1 PRISMA Flow Chart of Literature Review Search Results.....	56
2 CONSORT Flow Diagram for Comparing Mindfulness-Based <u>S</u> tress Reduction With the <u>H</u> ealth Enhancement Program in the Treatment of <u>U</u> rge Urinary Incontinence in Older Adult <u>W</u> omen (SHUW)	134
3 Design Overview	153
4 Process Measure Results, Graphed	205

ACKNOWLEDGMENTS

As I reach the culmination of my PhD work, I marvel at the tremendous support and guidance I have received. It has come in many forms and I acknowledge deep gratitude for each and every person and way. My chair, Dr. Kathie Supiano, for seeing in me what I could not yet see, for endless encouragement, direction, and the indefatigable amount of time spent in her role as my supervisory chair. My committee members, Dr. Mike Caserta, Dr. Angela Deneris, Dr. Jia-Wen Guo, and Dr. Paul Thielking, for their wealth of expertise and insightful assistance throughout this process. Vicki Overfelt and Amy Stevenson, the interventionists who both held the perfect combination of professional acumen and caring hearts. Dr. Ingrid Nygaard, for serving as my content expert and providing the inspiration for this work. Jan Baker, and Drs. Costa, Guarino, and Nygaard, for their prior innovative research on this topic. Dr. Daniel Adkins for his wise statistical direction. Trista Emmer and Djin Lai for both formatting and editing proficiency. My leaders and colleagues in the Gerontology Interdisciplinary Program and in the College of Nursing, for their belief and trust. My parents, Stig E. Friberg and Birgitta C. Spencer, for their academic examples, their faith in me, their high expectations I strive to meet, and their truly tireless support. My sister, Anna-Karin Smith, for her solidarity; she is more precious than an eye. My beloved boys, now men, Logan, Christian, and Bennett, for their unflagging love and their accommodation of my intense studies. And finally, my husband, Pat, who championed me throughout, in a

myriad of ways, seen and unseen.

Additionally, I convey deep gratitude to each entity who funded this dissertation: The Gamma Rho Chapter of Sigma Theta Tau International, the University of Utah Office of the Associate Vice President for Health Equity and Inclusion, and the University of Utah College of Nursing Noorda-Hartford Fellowship. Further, I acknowledge each scholarship and fellowship that sustained me over four years. It was an honor to be named a Marriner S. Eccles Fellow, a Jonas Nurse Leader Scholar, a Noorda-Hartford Fellow, and a Consortium for Families and Health Research (C-FAHR) Fellow.

.

CHAPTER 1

INTRODUCTION

Urge urinary incontinence is a highly troubling condition affecting as many as 50% of women 60 and older. This reported number may be underestimated, as only one in four women seek treatment for the condition. Urge urinary incontinence is more difficult to treat than stress urinary incontinence, and its challenging effects are seen across the spectrum of a woman's life, from emotional health to sexual activity. While stress urinary incontinence is typically resolved with physical therapy or surgery, urge urinary incontinence proves more refractory to many common urinary incontinence treatments. However, urge urinary incontinence may respond to noninvasive mind-body interventions, as this study explores.

1.1 Urinary Incontinence

1.1.1 Definition

Urinary incontinence is a lower urinary tract syndrome defined as the inability to hold urine in the bladder because voluntary control is lost, resulting in involuntary leakage (Abrams, Cardozo, et al., 2003; "Urinary incontinence," 2015). Urinary incontinence is one of the foremost geriatric syndromes, and yet it is underreported to health care providers (Ham, Sloane, Warshaw, Potter, & Flaherty, 2014; Mitteness, 1990). It is an undertreated syndrome in geriatric nursing facilities (Berlowitz, Brand, & Perkins, 1999; Lawhorne, Ouslander, Parmelee, Resnick, & Calabrese, 2008). While urinary incontinence is not a normal part of aging, it is often mistakenly assumed to be so (Doshi et al., 2010).

Urinary incontinence is typically classified by type: stress incontinence, urge incontinence, or "mixed," which is a combination of both stress and urge. Stress and urge

incontinence are clinically differentiated by a series of simple questions about urgency and physical activity (Brown et al., 2006; Holroyd-Leduc, Tannenbaum, Thorpe, & Straus, 2008; Rohr, Christensen, Ulstrup, & Kragstrup, 2004). Stress incontinence is characterized by leakage resulting from increased pressure on the bladder, for example, upon exertion, sneezing/coughing, or jumping (Haylen et al., 2010). The cause of stress incontinence is quite straightforward: It occurs when the pelvic floor muscle, or the urethral sphincter muscle at the neck of the bladder, is weakened (A. Deneris, personal communication, September 9, 2017). This is a structural disorder.

Urge incontinence is associated with a sudden need to urinate, and insufficient time to void in the toilet (Dumoulin & Hay-Smith, 2010). Typical precipitating events of urge incontinence are washing one's hands, the sound of running water, or a familiar sight or action signaling home—a garage door or unlocking the door to one's home. In the instance of a patient presenting with mixed urinary incontinence, one type is noted as predominant, for example, urinary incontinence, urge predominant. In this situation, the predominant type should be treated first (Thuroff et al., 2011).

Urge urinary incontinence is part of a larger constellation of symptoms, called overactive bladder, which includes urge frequency as well as nocturia (waking in the night due to need to urinate), but may or may not include incontinence (Abrams, Anderson, et al., 2010; Abrams, Cardozo, et al. 2003). The terms are sometimes used interchangeably, although this usage is often imprecise, since two-thirds of those with overactive bladder do not have urinary incontinence (Abrams, Cardozo, et al., 2003; Demaagd & Davenport, 2012). The most common type of urinary incontinence in older adults is urge urinary incontinence (Buckley, Lapitan, & Epidemiology Committee of the

Fourth International Consultation on Incontinence, 2010). The generally recognized definition of an older adult is an adult aged 65 or older (Gorman, 1999).

1.1.2 Prevalence

Urge urinary incontinence is common among the older adult population; up to 50% of those 60 and older report symptoms of urge urinary incontinence (Goode, Burgio, Richter, & Markland, 2010). Further, data indicate that only 1 of 4 women with urge urinary incontinence seek care (Minassian, Yan, Lichtenfeld, Sun, & Stewart, 2012). Urge urinary incontinence disproportionately affects older women and adversely affects health related quality of life (Coyne, Sexton, et al., 2008; Nitti, 2001). The effect of race and ethnicity on prevalence of urinary incontinence in older adult women is inconclusive, although at least one study has shown it is most prevalent in people of European descent, followed by people of Asian descent, and then people of African descent (Townsend, Curhan, Resnick, & Grodstein, 2010). In men, specifics regarding the incidence and severity of urinary incontinence over time are not well known (Ham et al., 2014). Urinary incontinence in men is increasing rapidly, as it correlates with surgical side effects of prostate cancer treatment (Ham et al., 2014). No data exist on the association of race and ethnicity on prevalence in the older adult male population (Goode et al., 2008; Tennstedt, Link, Steers, & McKinlay, 2008). This study focuses exclusively on urge urinary incontinence in women.

1.1.3 Impact

Urge urinary incontinence is also potentially traumatic, as it affects almost all areas of a woman's life (Markland, Richter, Fwu, Eggers, & Kusek, 2011). Involuntary leakage of urine affects one's social life, sexual activity, emotional well-being, health related quality of life, and risk for isolation (Bartoli, Aguzzi, & Tarricone, 2010; Coyne, Kvasz, et al., 2012; Coyne, Sexton, et al., 2008; Sims, Browning, Lundgren-Lindquist, & Kendig, 2011). Unlike stress urinary incontinence, which can typically be treated effectively with either physical therapy or surgery, urge urinary incontinence is more difficult to treat. This difficulty is alternately ascribed to detrusor muscle dysfunction or possible neural misregulation in the lower urinary tract (Banakhar, Al-Shaiji, & Hassouna, 2012). Symptoms of urge urinary incontinence can be the decisive factor that keeps older women from living independently: Over half of nursing facility admissions are related to incontinence (Coyne, Zhou, Thompson, & Versi, 2003). Thus, it may be particularly important to focus urge urinary incontinence research on the older adult female population.

1.1.4 Cost

Urinary incontinence is a costly chronic condition, estimated to reach \$83 billion by 2020 in the United States (Ganz et al., 2010; Milsom et al., 2014; Onukwugha et al., 2009). Cost is realized in a litany of ways: health care visits, diagnostic procedures, pads, behavioral therapies, pharmacotherapy, over the counter medications, sacral neuromodulation (the stimulation of the sacral nerves, through a surgical implant, allowing the person to perceive bladder fullness and completely empty the bladder)

(Hassouna, 2000; Elneil, 2012), surgery, caregiving, and relocation (Berlowitz et al., 1999; Cassells & Watt, 2003; Chong, Khan, & Anger, 2011; Coyne et al., 2014).

The cost of urge urinary incontinence affects the individual, the health system, the insurance structure and corporations, and long-term care facilities. Other less tangible costs are difficult to measure but still significant, including the eventual costs of social withdrawal and resulting isolation. These effects are realized across the age spectrum, from younger working women to community dwelling older adults and to those in nursing facilities (Bogner et al., 2002; Dubeau, Simon, & Morris, 2006; Fitzgerald, Palmer, Kirkland, & Robinson, 2002).

1.1.5 Significance

Beyond the areas of impact and cost discussed above, significance of a study to compare complementary treatment methods for older adult women with urge urinary incontinence is bolstered by the National Center for Complementary and Integrative Health's (NCCIH) 2016 strategic plan. The new plan includes such relevant objectives as “advance understanding of the mechanisms through which mind and body approaches affect health, resilience, and well-being” and “conduct studies in ‘real world’ clinical settings to test the safety and efficacy of complementary health approaches, including their integration into health care” (NCCIH, 2016, p. 5).

In addition to aligning with NCCIH's 2016 strategic plan, this study is also responsive to the Institute of Medicine's (now, National Academy of Sciences) 100 Initial Priority Topics for Comparative Effectiveness Research (2009) second quartile call to “compare the effectiveness of mindfulness-based interventions... in treating... chronic

diseases” (p. 3). It is time to address this chronic condition in an innovative way. New insights gained through this research will translate into new approaches to managing UUI, a highly prevalent and incommodious condition in older adult women.

1.2 Problem Statement

Older adult women with urge urinary incontinence are not sufficiently treated with current practices.

1.3 Purpose of the Study

The purpose of this study is to examine the feasibility of conducting a pilot randomized controlled trial comparing mindfulness-based stress reduction with the health enhancement program on symptoms of urge urinary incontinence in older adult women and to establish preliminary efficacy of these two approaches on symptoms of urge urinary incontinence.

1.4 Organization of Dissertation

This dissertation consists of eight chapters: The Introductory chapter, the Literature Review chapter, the Literature Review article, the Methods chapter, the Methods article, the Feasibility article, the Results chapter, and the Discussion chapter.

1.5 References

- Abrams, P., Andersson, K. E., Birder, L., Brubaker, L., Cardozo, L., Chapple, C.,... Members of Committees (2010). Fourth International Consultation on Incontinence recommendations of the International Scientific Committee: Evaluation and treatment of urinary incontinence, pelvic organ prolapse, and fecal incontinence. *Neurourology and Urodynamics*, 29(1), 213-240. doi:10.1002/nau.20870
- Abrams, P., Cardozo, L., Fall, M., Griffiths, D., Rosier, P., Ulmsten, U., ... Standardisation Sub-Committee of the International Continence Society. (2003). The standardisation of terminology in lower urinary tract function: Report from the Standardisation Sub-Committee of the International Continence Society. *Urology*, 61(1), 37-49.
- Banakhar, M. A., Al-Shaiji, T. F., & Hassouna, M. M. (2012). Pathophysiology of overactive bladder. *International Urogynecology Journal*, 23(8), 975-982. doi:10.1007/s00192-012-1682-6
- Bartoli, S., Aguzzi, G., & Tarricone, R. (2010). Impact on quality of life of urinary incontinence and overactive bladder: A systematic literature review. *Urology*, 75(3), 491-500.
- Berlowitz, D. R., Brand, H. K., & Perkins, C. (1999). Geriatric syndromes as outcome measures of hospital care: Can administrative data be used? *Journal of the American Geriatrics Society*, 47(6), 692-696.
- Bogner, H. R., Gallo, J. J., Sammel, M. D., Ford, D. E., Armenian, H. K., & Eaton, W. W. (2002). Urinary incontinence and psychological distress in community-dwelling older adults. *Journal of the American Geriatrics Society*, 50(3), 489-495.
- Brown, J. S., Bradley, C. S., Subak, L. L., Richter, H. E., Kraus, S. R., Brubaker, L., ... Diagnostic Aspects of Incontinence Study (DAISy) Research Group. (2006). The sensitivity and specificity of a simple test to distinguish between urge and stress urinary incontinence. *Annals of Internal Medicine*, 144(10), 715-723.
- Buckley, B. S., Lapitan, M. C., & Epidemiology Committee of the Fourth International Consultation on Incontinence. (2010). Prevalence of urinary incontinence in men, women, and children--current evidence: Findings of the Fourth International Consultation on Incontinence. *Urology*, 76(2), 265-270. doi:10.1016/j.urology.2009.11.078
- Cassells, C., & Watt, E. (2003). The impact of incontinence on older spousal caregivers. *Journal of Advanced Nursing*, 42(6), 607-616.
- Chong, E. C., Khan, A. A., & Anger, J. T. (2011). The financial burden of stress urinary incontinence among women in the United States. *Current Urology Reports*, 12(5), 358-362.

- Coyne, K. S., Kvasz, M., Ireland, A. M., Milsom, I., Kopp, Z. S., & Chapple, C. R. (2012). Urinary incontinence and its relationship to mental health and health-related quality of life in men and women in Sweden, the United Kingdom, and the United States. *European Urology*, 61(1), 88-95.
- Coyne, K. S., Sexton, C. C., Irwin, D. E., Kopp, Z. S., Kelleher, C. J., & Milsom, I. (2008). The impact of overactive bladder, incontinence and other lower urinary tract symptoms on quality of life, work productivity, sexuality and emotional well-being in men and women: Results from the EPIC study. *BJU International*, 101(11), 1388-1395. doi:10.1111/j.1464-410X.2008.07601.x
- Coyne, K. S., Wein, A., Nicholson, S., Kvasz, M., Chen, C. I., & Milsom, I. (2014). Economic burden of urgency urinary incontinence in the United States: A systematic review. *Journal of Managed Care Pharmacy*, 20(2), 130-140.
- Coyne, K. S., Zhou, Z., Thompson, C., & Versi, E. (2003). The impact on health-related quality of life of stress, urge and mixed urinary incontinence. *BJU International*, 92(7), 731-735.
- Demaagd, G. A., & Davenport, T. C. (2012). Management of urinary incontinence. *Pharmacy and Therapeutics*, 37(6), 345-361H.
- Doshi, A. M., Van Den Eeden, S. K., Morrill, M. Y., Schembri, M., Thom, D. H., Brown, J. S., & Group, R. R. F. I. S. A. K. R. (2010). Women with diabetes: Understanding urinary incontinence and help seeking behavior. *Journal of Urology*, 184(4), 1402-1407.
- Dubeau, C. E., Simon, S. E., & Morris, J. N. (2006). The effect of urinary incontinence on quality of life in older nursing home residents. *Journal of the American Geriatric Society*, 54(9), 1325-1333. doi:10.1111/j.1532-5415.2006.00861.x
- Dumoulin, C., & Hay-Smith, J. (2010). Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database of Systematic Reviews*, 1(1), 1-51.
- Elneil, S. (2012). Sacral neuromodulation in pelvic floor disorders. *Pelvic Floor Disorders*. Retrieved from www.neuromodulation.com/for-patients.
- Fitzgerald, S. T., Palmer, M. H., Kirkland, V. L., & Robinson, L. (2002). The impact of urinary incontinence in working women: A study in a production facility. *Women and Health*, 35(1), 1-16. doi:10.1300/J013v35n01_01
- Ganz, M. L., Smalarz, A. M., Krupski, T. L., Anger, J. T., Hu, J. C., Wittrup-Jensen, K. U., & Pashos, C. L. (2010). Economic costs of overactive bladder in the United States. *Urology*, 75(3), 526-532, 532 e521-518. doi:10.1016/j.urology.2009.06.096
- Goode, P. S., Burgio, K. L., Redden, D. T., Markland, A., Richter, H. E., Sawyer, P., &

- Allman, R. M. (2008). Population based study of incidence and predictors of urinary incontinence in Black and White older adults. *Journal of Urology*, 179(4), 1449-1453; discussion 1453-1444. doi:10.1016/j.juro.2007.11.069
- Goode, P. S., Burgio, K. L., Richter, H. E., & Markland, A. D. (2010). Incontinence in older women. *Journal of the American Medical Association*, 303(21), 2172-2181. Retrieved from http://jama.jamanetwork.com/data/Journals/JAMA/4515/jca05002_2172_2181.pdf
- Gorman, M. (1999). Development and the rights of older people. In J. Randel et al. (Eds.) *The ageing and development report: Poverty, independence and the world's older people* (pp. 3-21). London, Earthscan Publications Ltd.
- Ham, R. J., Sloane, P. D., Warshaw, G. A., Potter, J. F., & Flaherty, E. (2014). *Ham's primary care geriatrics: A case-based approach*. Philadelphia, PA: Mosby Elsevier.
- Hassouna, M. M., Siegel, S. W., Nyeholt, A. A., Elhilali, M. M., van Kerrebroeck, P. E., Das, A. K., ... Schmidt, R. A. (2000). Sacral neuromodulation in the treatment of urgency-frequency symptoms: A multicenter study on efficacy and safety. *Journal of Urology*, 163(6), 1849-1854.
- Haylen, B. T., De Ridder, D., Freeman, R. M., Swift, S. E., Berghmans, B., Lee, J., ... Schaer, G. N. (2010). An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. *International Urogynecology Journal*, 21(1), 5-26. Retrieved from <http://link.springer.com/article/10.1007%2Fs00192-009-0976-9>
- Holroyd-Leduc, J. M., Tannenbaum, C., Thorpe, K. E., & Straus, S. E. (2008). What type of urinary incontinence does this woman have? *Journal of the American Medical Association*, 299(12), 1446-1456. doi:10.1001/jama.299.12.1446
- Institute of Medicine. (2009). *100 initial priority topics for comparative effectiveness research*. Washington, DC: National Academy of Sciences.
- Lawhorne, L. W., Ouslander, J. G., Parmelee, P. A., Resnick, B., & Calabrese, B. (2008). Urinary incontinence: A neglected geriatric syndrome in nursing facilities. *Journal of the American Medical Directors Association*, 9(1), 29-35. doi:10.1016/j.jamda.2007.08.003
- Markland, A. D., Richter, H. E., Fwu, C. W., Eggers, P., & Kusek, J. W. (2011). Prevalence and trends of urinary incontinence in adults in the United States, 2001 to 2008. *Journal of Urology*, 186(2), 589-593. doi:10.1016/j.juro.2011.03.114
- Milsom, I., Coyne, K. S., Nicholson, S., Kvasz, M., Chen, C. I., & Wein, A. J. (2014). Global prevalence and economic burden of urgency urinary incontinence: A

- systematic review. *European Urology*, 65(1), 79-95.
doi:10.1016/j.eururo.2013.08.031
- Minassian, V. A., Yan, X., Lichtenfeld, M. J., Sun, H., & Stewart, W. F. (2012). The iceberg of health care utilization in women with urinary incontinence. *International Urogynecology Journal*, 23(8), 1087-1093. doi:10.1007/s00192-012-1743-x
- Mitteness, L. S. (1990). Knowledge and beliefs about urinary incontinence in adulthood and old age. *Journal of the American Geriatrics Society*, 38(3), 374-378.
- National Center for Complementary and Integrative Health. (2016). *2016 strategic plan: Exploring the science of integrative health*. Bethesda, MD: National Institutes of Health.
- Nitti, V. W. (2001). The prevalence of urinary incontinence. *Reviews in Urology*, 3 Suppl 1, S2-6.
- Onukwugha, E., Zuckerman, I. H., McNally, D., Coyne, K. S., Vats, V., & Mullins, C. D. (2009). The total economic burden of overactive bladder in the United States: A disease-specific approach. *American Journal of Managed Care*, 15(4 Suppl), S90-97.
- Rohr, G., Christensen, K., Ulstrup, K., & Kragstrup, J. (2004). Reproducibility and validity of simple questions to identify urinary incontinence in elderly women. *Acta Obstetrica et Gynecologica Scandinavica*, 83(10), 969-972.
doi:10.1111/j.0001-6349.2004.00557.x
- Sims, J., Browning, C., Lundgren-Lindquist, B., & Kendig, H. (2011). Urinary incontinence in a community sample of older adults: Prevalence and impact on quality of life. *Disability and Rehabilitation*, 33(15-16), 1389-1398.
- Tennstedt, S. L., Link, C. L., Steers, W. D., & McKinlay, J. B. (2008). Prevalence of and risk factors for urine leakage in a racially and ethnically diverse population of adults: The Boston Area Community Health (BACH) Survey. *American Journal of Epidemiology*, 167(4), 390-399. doi:10.1093/aje/kwm356
- Thuroff, J. W., Abrams, P., Andersson, K. E., Artibani, W., Chapple, C. R., Drake, M. J., ... Tubaro, A. (2011). EAU guidelines on urinary incontinence. *European Urology*, 59(3), 387-400. doi:10.1016/j.eururo.2010.11.021
- Townsend, M. K., Curhan, G. C., Resnick, N. M., & Grodstein, F. (2010). The incidence of urinary incontinence across Asian, Black, and White women in the United States. *American Journal of Obstetrics and Gynecology*, 202(4), 378 e371-377.
doi:10.1016/j.ajog.2009.11.021
- Urinary incontinence: Causes, treatments, symptoms. (2015). *Medical News Today*. Bexhill-on-Sea, UK: MediLexicon International Ltd.

CHAPTER 2

LITERATURE REVIEW

Urge urinary incontinence (UUI) in older adult women is a distressing and understudied problem. UUI is correlated with “significant morbidity and reduced quality of life” (DeMaagd, 2012, p. 345). While it is associated with aging, it is often not documented at time of hospital discharge and is a neglected syndrome in care facilities as it is assumed to be a normal part of growing older. UUI also carries a social stigma, often causing those with the condition to withdraw from social opportunities, inflicting additional isolation during a vulnerable period of life.

2.1 Urge Urinary Incontinence

2.1.1 Risk Factors and Etiology

The susceptibility and severity of UUI have been discussed in the introductory chapter. It is also important to understand the risk factors, etiology, and characteristics of this condition. Risk factors for urinary incontinence include age, female gender, obesity, depression, diabetes, hysterectomy, and functional impairment (DuBeau, Kuchel, & Johnson, 2009; Melville, Katon, Delaney, & Newton, 2005). Historically, urge urinary incontinence has been understood to be caused by bladder dysfunction, poor muscle tone in the pelvic floor, obesity, nerve dysfunction, or a combination of these (Andersson, 2002; Fowler, Griffiths, & de Groat, 2008; Griffiths, Tadic, Schaefer, & Resnick, 2007; Subak et al., 2009). While these causes may explain some urge urinary incontinence, they do not account for all cases. Recent research suggests that urge urinary incontinence may be due to abnormal function within the brain, rather than within the nervous system or bladder (Baker, Costa, Guarino, & Nygaard, 2014; Baker, Costa, & Nygaard, 2012). Urge urinary incontinence is, to some degree, a functional rather than a structural disorder,

resulting from an “abnormal perception or interpretation of physiologic events” (Baker et al., 2014, p. 143). In a pilot study and a subsequent randomized pilot study, Baker and colleagues found that mindfulness-based stress reduction training significantly reduced leakage episodes per day, overactive bladder symptoms, and health related quality of life (Baker et al., 2014). Impressively, these results were maintained at 1-year follow-up. These findings invite the exploration of relevant variables and the relationships between them.

2.1.1.1 Characteristics

Urge urinary incontinence is measured by two basic symptoms, severity and bother. These are discrete from one another, and are measured separately. Many strategies, instruments, and scales are utilized in research studies to measure these symptoms.

2.1.1.1.1 Severity

The severity of urinary incontinence escalates with age (Hannestad, Rortveit, Sandvik, Hunskaar, & Norwegian, 2000). Symptom severity of urge urinary incontinence is measured by episodes of leakage per day. This can be measured by having the patient complete a voiding diary, which is a record of when the leakage occurred, under what conditions, and the estimated amount of leakage (J. Baker, personal communications, October 2015). The Incontinence Severity Index can also be administered to assess symptom severity (Hanley, Capewell, & Hagen, 2001; Klovning, Avery, Sandvik, & Hunskaar, 2009). It shows good validity and adequate internal consistency ($\alpha = 0.76$)

(Black, Griffiths, & Pope, 1996; Murphy et al., 2006).

2.1.1.1.2 Bother

Distinct from urge urinary incontinence symptom severity is the concept of bother. Bother is defined as the impact that urge urinary incontinence has on the individual (FitzGerald, Butler, Shott, & Brubaker, 2002). The experience of bother should not be dismissed as its effects are impactful on the individual's quality of life (Oh & Ku, 2007; Penson, 2013; Sexton et al., 2011; van der Vaart, de Leeuw, Roovers, & Heintz, 2002). Unfortunately, older women often resign themselves to their urge urinary incontinence symptoms, assuming that the syndrome is inevitable and unsolvable. This perception can lead to a restricted lifestyle and eventual loss of autonomous living arrangements (Gaugler, Duval, Anderson, & Kane, 2007; Morrison & Levy, 2006). Bother can specifically be measured by measuring health related quality of life in urge urinary incontinent patients (Coyne et al., 2003). Bother is measured by administering the Overactive Bladder Questionnaire; in older adult populations, the Short Form is typically utilized (Abrams, Smith, & Cotterill, 2015; Kwak, Kwon, & Kim, 2015; Tang et al., 2014) or the Patient Global Impression of Improvement scale (Srikrishna, Robinson, & Cardozo, 2010).

2.1.1.2 Treatments

Current clinical management of urge urinary incontinence is achieved in a ladder-wise fashion (Hersh & Salzman, 2013). Cognitive behavioral therapy, such as bladder training, is generally the first prescribed method. If this is not sufficient in treating

symptoms, pharmacologic avenues are explored. Behavioral and pharmacologic therapies may also be combined, and this may increase treatment success. Further medical treatments have also been utilized. Finally, some complementary and integrative therapies are being explored to treat urge urinary incontinence. Unfortunately, current treatment effects are modest, and gaps in the literature that guides women's treatment choices are wide. Long term follow-up data on treatment effects are weak or absent, and potential harm and side effects are not well described (Hartmann et al., 2009).

2.1.1.2.1 Behavioral Therapy

The current first line of treatment for urge urinary incontinence is behavioral therapy. Behavioral therapy may consist of education, biofeedback, use of voiding diaries, scheduling or postponing voiding, avoiding caffeine use, or strengthening the pelvic floor (Burgio, 2009; Cardozo, 2000; Dumoulin & Hay-Smith, 2010; Milne, 2008; Wang, 2000; Wang, Wang, & Chen, 2004; Wyman, Burgio, & Newman, 2009). Several studies have shown reduction of symptoms with behavioral therapy programs, although participant satisfaction rates varied (Burgio et al., 2002; Diokno et al., 2004; Dumoulin & Hay-Smith, 2010; Wyman et al., 2009). Behavioral therapy has a few caveats: Adherence tends to be low, there are few skilled practitioners who offer it, it requires many visits, and as such can be both time consuming and expensive (I. Nygaard, personal communication, 23 November 2015). Behavioral therapies reportedly reduce leakage episodes up to 1.9 per day (Hartmann et al., 2009).

2.1.1.2.2 Pharmacologic Therapy

Pharmacologic treatments are designed to be a second line of treatment (Nabi, Cody, Ellis, Herbison, & Hay-Smith, 2006). The most common class of medications used for urge urinary incontinence treatment is anticholinergics. Anticholinergics block acetylcholine (muscarinic) signals to the brain, which trigger the abnormal contractions associated with urge urinary incontinence. Anticholinergic medications reduce the number of leakage episodes to between 1.5–2.5 per day (Hartmann et al., 2009). These medications are designed to relax the bladder, yet side effects and contraindications are numerous and often dangerous. High rates of discontinuation in patients taking anticholinergics are reported, not only in older adult women but younger women and men as well (Gopal, Haynes, Bellamy, & Arya, 2008). Serious central nervous system side effects, including falls, confusion, sleep disruption and psychosis, are often seen in patients taking anticholinergic medication (Franco, 2011). These unwelcome anticholinergic side effects are more troubling in an older population, where a serious fall or confusion threatens the independence of the individual. Both older age and female gender are significantly associated with adverse drug reaction related hospital admissions; as such, pharmacologic treatment carries more severe risk for older adult women (Mannesse, Derkx, De Ridder, & van der Cammen, 2000). Additionally, these medications tend to show reduced efficacy with long-term use (Kelleher, Cardozo, Khullar, & Salvatore, 1997). Hence, older adult women are a crucial population in which to study alternate treatment methods.

2.1.1.2.3 Combined Therapy

Regrettably, neither behavioral nor pharmaceutical treatments delivers reliable, satisfactory long-term outcomes; in fact, a single management modality is not likely to entirely resolve women's symptoms of urge urinary incontinence (Hartmann et al., 2009). Behavioral therapy and pharmacologic therapy are often used in conjunction to treat urge urinary incontinence (Borello-France et al., 2010; Burgio et al., 2010; Goode et al., 2011; Wyman, Harding et al., 2010; Wyman, Klutke et al., 2010). A Cochrane review of anticholinergics versus nonpharmacological therapies for overactive bladder syndrome reported that better results (e.g., fewer leakage episodes) were reported when pharmacologic and behavior therapy were used in tandem (Alhasso, McKinlay, Patrick, & Stewart, 2006). In contrast, a more recent RCT showed lack of improvement when adding behavioral therapy to an existing pharmacologic treatment regimen (Burgio et al., 2010). While care providers may use behavioral therapy to wean a patient off of medication, a recent study showed unsustained satisfaction with behavior treatment after discontinuation of pharmacologic treatment (Burgio, 2009; Burgio et al., 2008; Milne, 2008).

2.1.1.2.4 Further Therapies

When urge urinary incontinence proves refractory to medication and behavioral therapies, other alternative medical therapies are explored. However, many of these therapies have been found to be invasive and not efficacious. One such treatment is the use of botulinum toxin A (Botox®; Petrou et al., 2009; Shepherd, Lowder, Leng, & Smith, 2011; Visco et al., 2012). The main concern with this treatment is that as many as

half of patients are left with “transient post-void residual urine increase,” which is a severe, negative side effect (Brubaker et al., 2008). A 2008 systematic review found “clinically significant improvement,” although it called for more appropriately powered and designed studies. In addition, several of the article’s authors are consultants for Allergan, the company that produces Botox® (Karsenty et al., 2008). A later study also found this same negative side effect of transient urinary retention as well as a higher rate of urinary tract infections as compared to anticholinergic therapy (Visco et al., 2012). Another treatment is neuromodulation of sacral nerves, which has shown encouraging outcomes in women of all ages, ranged 17–81 years old (Abrams, Cardozo, et al., 2003; Hassouna et al., 2000; Siegel et al., 2000). Still, sacral neuromodulation is an invasive and expensive treatment option for urge urinary incontinence, and complications include patient pain at the site of implantation as well as lead migration (Schmidt et al., 1999). Several authors, including Shamliyan, Kane, Wyman, and Wilt in their systematic review, concur that the effects of sacral modulation and botulism injections are inconsistent and the current indications are not sufficient to guide selection for patients with urge urinary incontinence (Hartmann, 2009; Shamliyan, Kane, Wyman, & Wilt, 2008).

2.1.1.2.5 Complementary and Integrative Therapy

Complementary health practices refer to individualized, holistic treatments which use natural medicinal products developed outside of conventional medicine, and/or nonpharmacologic therapies such as acupressure or massage (Kienle et al., 2011). These are systems, products, and practices “not generally considered part of conventional

medicine” (“Complementary,” 2015). The National Center for Complementary and Integrative Health, a division of the National Institutes of Health, and formerly named the National Center for Complementary and Alternative Medicine, uses the term *complementary health approaches* when “discuss[ing] practices and products of nonmainstream origin,” while the term *integrative health* is used to describe “incorporating complementary approaches into mainstream health care” (“Complementary,” 2015). It is estimated that approximately 11% of Americans’ health care costs are spent on complementary and integrative health practices, products, or services (Nahin et al., 2007).

It is uncertain how frequently complementary and integrative therapies have been used to treat urge urinary incontinence, but investigations of these approaches are becoming more common in the scientific literature. Potential complementary, integrative, and alternative therapies have not yet been sufficiently studied for definitive recommendations to be made (Cherniack, 2006).

Acupuncture for overactive bladder has been studied in a pilot study, a randomized controlled trial, and most recently in a review, by separate research teams (Bergstrom, Carlsson, Lindholm, & Widengren, 2000; Emmons & Otto, 2005; Paik et al., 2013). The pilot study found “significant improvements” (Bergstrom et al. 2000, p. 179) after 12 acupuncture treatments, with improvement sustained at 3-month follow-up. This study did not include a control condition. The randomized controlled trial showed decreases in episodes of incontinence in both the treatment and placebo conditions but saw “no significant difference in the change between the groups” (Emmons & Otto, 2005, p. 138). The review examined several RCTs and found that the results “failed to

demonstrate any statistically significant improvements in urinary incontinence” (Paik et al., 2013).

Elstad and colleagues (2011) report that Hispanic populations use herbal drinks to treat urinary incontinence. Loera and colleagues (2001) show that Hispanics most commonly using herbs are female, older than 75, living independently, and experiencing financial strain. Typical drinks include agua fresca, maize silk, and horsetail. The use of these herbal medicines has not been shown to reduce urinary symptoms (Elstad, Maserejian, McKinlay, & Tennstedt, 2011; Loera, Black, Markides, Espino, & Goodwin, 2001).

Two recent studies explored the practice of yoga in treating urge urinary incontinence in women, although not specifically in older adults (Huang, Jenny, Chesney, Schembri, & Subak, 2014; Tenfelde & Janusek, 2014). Huang and colleagues administered a yoga intervention and saw overall incontinence reduced by 66% in the yoga condition compared with 13% in the waitlist control condition, but these improvements were only observed in the stress incontinent participants (Huang et al., 2014). No significant reduction in episodes of incontinence were observed in the urge incontinent participants.

In an earlier study, an autonomic nervous system imbalance was detected in women with overactive bladder syndrome (OAB), of which urge urinary incontinence is a part (Hubeaux, Deffieux, Ismael, Raibaut, & Amarenco, 2007). Specifically, sympathetic tone “increased significantly in women with OAB at the end of bladder filling,” while in women with stress urinary incontinence, it did not. Women with urge urinary incontinence presented with this autonomic nervous system imbalance while

women with stress urinary incontinence displayed autonomic nervous system balance. Two subsequent studies reproduced this autonomic nervous system difference between urge urinary incontinent and stress urinary incontinent participants (Hubeaux et al., 2011; Im, Kim, Kim, & Choi, 2010). Tenfelde and Janusek discussed the possibility that meditative approaches may correct this autonomic nervous system imbalance that women with urge urinary incontinence have been shown to have (Tenfelde & Janusek, 2014).

Various treatments have been applied to the urge urinary incontinent older adult female population. Traditionally, behavioral and/or pharmacologic therapies have been prescribed, recommended, or administered. The decreasing efficacy of pharmacologic treatment and the tendency for women with urge urinary incontinence to need to involve multicomponent behavioral therapy indicate a need for new, more effective treatment options (Hartmann et al., 2009; Tenfelde & Janusek, 2014).

2.1.2 Problem Statement

Older adult women with urge urinary incontinence are not sufficiently treated with current practices.

2.2 Theoretical Framework

To explore promising potential treatments for urge urinary incontinence, it is important to examine the mental and emotional factors of urge urinary incontinence. The psychological component of urge urinary incontinence can be viewed through the lens of two theories: stress process theory and the concept of self-efficacy. Stress process theory, as defined by Pearlin and colleagues, has a role in explaining why women persistently

experience urge urinary incontinence (Pearlin, Lieberman, Menaghan, & Mullan, 1981; Pearlin, Schieman, Fazio, & Meersman, 2005). The concept of self-efficacy, developed by Albert Bandura, may explain how a mind–body treatment could reduce the symptoms and impact of urge urinary incontinence (Bandura, 1977, 1990, 2004; Bandura, Caprara, Barbaranelli, Gerbino, & Pastorelli, 2003; Bandura, Cioffi, Taylor, & Brouillard, 1988; Bandura & Locke, 2003). These two theories offer context for possible efficacious treatment of urge urinary incontinence.

2.2.1 Stress Process Theory

The Oxford English Dictionary (Simpson, Weiner, & Oxford University, 1989) defines stress as, “An adverse circumstance that disturbs, or is likely to disturb, the normal physiological or psychological functioning of an individual; such circumstances collectively. Also, the disturbed state that results.” Stress process theory posits that people develop stress when they are exposed to chronic strain and undergo eventful experiences, and that this stress results in negative health outcomes (Pearlin et al., 1981; Pearlin et al., 2005). Stress process theory has been applied to explain correlations in health disparities and socioeconomic status (McEwen & Gianaros, 2010; Thoits, 2010; Turner, 2010). Gender inequalities can magnify people’s exposure to stress (Thoits, 2010). While short-term stress process can be protective, long-term stress process is typically damaging; conditions which are chronically stressful cause deterioration in both brain and body (McEwen & Gianaros, 2010). Older adults are often exposed to long-term stress in the form of loss of relationships, social status, and/or job identity. The negative effects may then be seen in both mind and body. Stress process theory may be used to

explain the mind–body connection of stress to urge urinary incontinence, and, as eventful change is unavoidably part of the aging process, may be particularly applicable to the experience in older adult women.

Stress has both psychological and physical consequences. The mental and emotional strain of stress, psychological in nature, can express itself physiologically. Lai and colleagues (2015) measured psychological stress in urinary incontinent individuals and found that participants with overactive bladder had psychological stress levels significantly higher than healthy controls (Lai, Gardner, Vetter, & Andriole, 2015). Psychological stress in this study was measured with the Perceived Stress Scale (Cohen, Kamarck, & Mermelstein, 1983). This study showed a positive correlation between stress levels and symptoms of urinary incontinence ($p = .007$) and impact on quality of life ($p = .029$). Stress can contribute to a diminishment of self-concept (Pearlin et al., 1981). According to stress process theory, stress and its accompanying feelings of self-diminishment are counteracted by strengthening self-concept, through mastery and self-esteem building. I will measure stress with Cohen’s Perceived Stress Scale (Cohen, Kamarck, & Mermelstein, 1983).

2.2.2 Self-Efficacy

According to Thoits (2010), “the impacts of stressors on health and wellbeing are reduced when persons have high levels of mastery, [and] self-esteem” (p. 41). Mastery and self-esteem building associated with stress reduction can be partially explained by the concept of self-efficacy. Albert Bandura, the pioneer in developing this concept, defines perceived self-efficacy as “people’s beliefs in their capabilities to produce given

attainments” (Bandura, 2006, p. 307). Bandura’s self-efficacy theory addresses perceived task capability through mastery experiences (Bandura, 2006). These accumulated mastery experiences can lead to transformational restructuring of efficacy beliefs, the belief that one can manage a stressful situation. Efficacy beliefs influence whether people think erratically or strategically, as well as optimistically or pessimistically. According to Bandura, perceived self-efficacy affects self-development and adaptation (Bandura et al., 2003). Prior studies of older adults have shown that lower self-efficacy is associated with reduced physical function, and, in contrast, higher levels of self-efficacy correlate with lower rates of disability (Aggarwal et al., 2014; Femia, Zarit, & Johansson, 1997). Several studies have shown greater self-efficacy resulting in positive outcomes for older adults in varied areas, recovery from falls, fractures, and coronary surgery (Carroll, 1995; Fortinsky et al., 2002; Tinetti, Mendes de Leon, Doucette, & Baker, 1994).

According to Tannenbaum (2008), psychological factors such as self-efficacy may also play an important role in explaining urinary incontinence and its control. While encouraging preliminary results of a small intervention trial (Kim, 2001) had shown increased self-efficacy in participants with stress urinary incontinence, the potential effects of interventions could only be accurately measured with a validated urinary incontinence questionnaire incorporating self-efficacy specifically for geriatric urinary incontinence. Tannenbaum and colleagues developed an evaluative instrument to assess self-efficacy for preventing or reducing urinary incontinence, the Geriatric Self-Efficacy Index for Urinary Incontinence (2008).

I will measure self-efficacy with an adapted version of the Geriatric Self-Efficacy Index for Urinary Incontinence (GSE-UI). As I explored the self-efficacy scales, I found

the GSE-UI to be the best fit for my intervention. For the sake of simplicity and elegance in my research design, I added one question addressing self-efficacy in the intervention at hand, regarding the confidence of applying the elements of the intervention to manage urinary incontinence (see Section 4.12.12).

2.3 Mindfulness-Based Stress Reduction

Mindfulness-based stress reduction (MBSR) is a skill defined as “moment to moment awareness” (Grossman, Niemann, Schmidt, & Walach, 2004, p. 36), which is nonjudgmental and believed to promote wellbeing (Brown & Ryan, 2003). Mindfulness-based stress reduction training was pioneered by Jon Kabat-Zinn in the late 1970s, and has shown long-lasting improvement of physical and mental health variables such as coronary artery disease and depression, a positive change in the attitudes and perceptions of participants with fibromyalgia and cancer, and reduced mood disturbances such as anxiety disorder and increased self-esteem (Grossman, 2004; Kabat-Zinn, 2003; Segal, Williams, & Teasdale, 2013). Mindfulness-based stress reduction has been applied to general populations of all ages as well as such diverse populations as medical school students and prisoners (Grossman, 2004; Moss, 2015; Samuelson, 2007). Mindfulness-based stress reduction is taught as a series of eight 2-hour group sessions, with a full day retreat between weeks 6 and 7 (Kabat-Zinn, 2005). Participants learn both formal and informal ways to apply mindfulness to their daily lives. Mindfulness teaches participants to carefully attend to one thing at a time, and to notice thoughts and physical sensations without passing judgment (Kilpatrick et al., 2011). Practitioners learn to notice their environment and activities with a commitment to stay in the present moment.

Mindfulness training improves attention-related behavioral responses (Jha, Krompinger, & Baime, 2007). It has been shown to regulate visceral awareness and improve self-regulation (Holzel et al., 2007). Mindfulness-based stress reduction has been proven a useful intervention for a “broad range of chronic disorders and problems” (Grossman, 2004).

A recent systematic review of MBSR conducted by Fjorback and colleagues (2011) showed impressive breadth of application across populations, such as medical students, women with fibromyalgia, community residents, recurrently depressed patients, and women with breast cancer. This systematic review also showed mindfulness-based stress reduction programs applied to a variety of conditions, such as anxiety, emotional distress, multiple sclerosis, rheumatoid arthritis, and COPD. MBSR showed demonstrable effects, with the review concluding that mindfulness-based stress reduction is recommended as “a useful method for improving mental health and reducing symptoms of stress, anxiety and depression, ... and recommended in medical disease management to improve health-related quality of life” (Fjorback, Arendt, Ørnbøl, Fink, & Walach, 2011).

2.3.1 Application of MBSR in Older Adults

Mindfulness-based stress reduction has been used to treat a multitude of illnesses and conditions in older adults. The apparent connection between the mind and the body is germane to many biophysical processes (Chiesa & Serretti, 2010; Franco, 2011; Jha et al., 2007). Research has been done regarding the precise components of mindfulness that produce positive outcomes in community dwelling older adults (Gallegos et al., 2013).

Gallegos and colleagues (2013) studied the effects of specific MBSR activities, including yoga, sitting meditation, informal meditation, and body scanning on immune function, as measured by IL-6, on insulin-like growth factor concentrations, measured by IGF-1 levels, and positive affect as measured by the Positive and Negative Affect Schedule (Watson, Clark, & Tellegen, 1988). Stronger immune function and more positive affect were both observed (Gallegos, 2013).

In the older adult population, MBSR has already been successfully utilized to treat mood disturbances, loneliness, emotional distress, and improve executive function (Creswell et al., 2012; Lenze et al., 2014; Moynihan et al., 2013; Young & Baime, 2010). In a sample of older adults living in a continuing care retirement community, MBSR participants reported “significantly greater improvement in acceptance and psychological flexibility in role limitations due to physical health... [and] increased awareness, less judgment, and greater self-compassion” (Moss, 2015). Mindfulness-Based Stress Reduction has been studied in minority and low-income older adult populations (Szanton, Wenzel, Connolly, & Piferi, 2011). Szanton and colleagues (2011) conducted focus groups with African American women over 60 in low-income housing to understand “which parts of MBSR were most important...and whether they apply their training to daily challenges” (p. 1). They discovered that participants found MBSR particularly useful when undergoing medical procedures as well as dealing with depression and managing anger.

Mindfulness-Based Stress Reduction is a specific type of mindfulness meditation. More broadly, mindfulness has also been used to successfully treat chronic pain and other chronic conditions, including high blood pressure, in the older adult population, as well

as irritable bowel syndrome in the general population (Gaylord et al., 2009; Morone, Greco, & Weiner, 2008; Palta et al., 2012).

Of particular interest, studies using mindfulness in persons with irritable bowel syndrome may suggest that IBS is a chronic condition quite similar to urge urinary incontinence in nature. While it has not been used in an older adult population, the success of a mindfulness intervention in IBS participants is particularly promising due to the similar results found when imaging the brain of patients with these disorders (Chang, 2005; Garland et al., 2012; Gaylord et al., 2009). Functional neuroimaging studies reveal different regional brain activation responses, related to alterations in perception. Specifically, this exaggerated activation occurs in the emotional (anterior cingulate) cortex (Griffiths & Tadic, 2008). These differences occur in areas of the brain associated with attentional processes as well as response selection (Chang, 2005). Mindfulness enhances specific components of attention (Jha et al., 2007). Patients with irritable bowel syndrome and urge urinary incontinence both appear to catastrophize their experiences, and this heightened visceral sensitivity increases the likelihood of future episodes (Baker, 2012; Chang, 2005). Catastrophizing is a cognitive distortion in which the person not only predicts a negative outcome but also assumes that if the negative outcome occurred it would be a disaster (Boyes, 2013).

Coyne and colleagues (2009) report heightened sensitivity of bladder urgency, mood disturbances accompanying these perceptions, and high levels of “psychiatric morbidity” (p. 4) in individuals with urge urinary incontinence. Mindfulness may cultivate a nonreactive (a more calm, less reactive) mindset, which lowers the visceral sensitivity and thus also lowers the evaluation and judgment of threat in the situation

(Garland et al., 2012). Mindfulness may prove to be a fitting psychosocial intervention for urge urinary incontinence in older adult women; in fact, Baker and colleagues (2012) suggest MBSR may be “uniquely suited to treat the underlying psychological and physical symptoms associated with urge urinary incontinence” (p. 46). This study will be the first to compare the usefulness of MBSR versus the Health Enhancement Program, an active comparison condition, in older adult women.

2.3.2 A Synthesis of Theories

Stress process theory and the concept of self-efficacy contribute to an understanding of the mind–body relationship in urge urinary incontinence. One’s self-beliefs, as theorized in the concept of self-efficacy, are linked to an individual’s management of stress. Mindfulness-based stress reduction, with its acquired skills of psychological self-regulation, may offer an opportunity for individuals with urge urinary incontinence to increase self-efficacy. Mindfulness-based stress reduction skills could facilitate cognitive-emotional self-regulation that increases self-efficacy, reduces the stress associated with UUI and its associated severity and bother.

Chapter 3 supplies the accompanying formal literature review.

2.4 References

- Abrams, P., Blaivas, J. G., Fowler, C. J., Fourcroy, J. L., Macdiarmid, S. A., Siegel, S. W., & Van Kerrebroeck, P. (2003). The role of neuromodulation in the management of urge urinary incontinence. *BJU International*, 91(4), 355-359.
- Abrams, P., Smith, A. P., & Cotterill, N. (2015). The impact of urinary incontinence on health-related quality of life (HRQoL) in a real-world population of women aged 45-60 years: Results from a survey in France, Germany, the UK and the USA. *BJU International*, 115(1), 143-152. doi:10.1111/bju.12852
- Aggarwal, N. T., Wilson, R. S., Beck, T. L., Rajan, K. B., Mendes de Leon, C. F., Evans, D. A., & Everson-Rose, S. A. (2014). Perceived stress and change in cognitive function among adults 65 years and older. *Psychosomatic Medicine*, 76(1), 80-85. doi:10.1097/PSY.0000000000000016
- Alhasso, A. A., McKinlay, J., Patrick, K., & Stewart, L. (2006). Anticholinergic drugs versus non-drug active therapies for overactive bladder syndrome in adults. *Cochrane Database of Systematic Reviews*, (4), CD003193. doi:10.1002/14651858.CD003193.pub3
- Andersson, K. E. (2002). Bladder activation: Afferent mechanisms. *Urology*, 59(5 Suppl 1), 43-50.
- Baker, J., Costa, D., Guarino, J. M., & Nygaard, I. (2014). Comparison of mindfulness-based stress reduction versus yoga on urge urinary incontinence: A randomized pilot study with 6-month and 1-year follow-up visits. *Female Pelvic Medicine and Reconstructive Surgery*, 20(3), 141-146. doi:10.1097/spv.0000000000000061
- Baker, J., Costa, D., & Nygaard, I. (2012). Mindfulness-based stress reduction for treatment of urge urinary incontinence: A pilot study. *Female Pelvic Medicine and Reconstructive Surgery*, 18(1), 46-49. doi:10.1097/SPV.0b013e31824107a6
- Bandura, A. (1977). Self-efficacy: Toward a unifying theory of behavioral change. *Psychological Review*, 84(2), 191-215.
- Bandura, A. (1990). Self-regulation of motivation through anticipatory and self-reactive mechanisms. *Nebraska Symposium on Motivation*, 38, 69-164. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/2130260>
- Bandura, A. (1997). The anatomy of stages of change. *American Journal of Health Promotion*, 12(1), 8-10.
- Bandura, A. (2004). Health promotion by social cognitive means. *Health Education & Behavior*, 31(2), 143-164. doi:10.1177/1090198104263660
- Bandura, A. (2006). Toward a psychology of human agency. *Perspectives on Psychological Sciences*, 1(2), 164-180. doi:10.1111/j.1745-6916.2006.00011.x

- Bandura, A., Caprara, G. V., Barbaranelli, C., Gerbino, M., & Pastorelli, C. (2003). Role of affective self-regulatory efficacy in diverse spheres of psychosocial functioning. *Child Development*, 74(3), 769-782. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/12795389>
- Bandura, A., Cioffi, D., Taylor, C. B., & Brouillard, M. E. (1988). Perceived self-efficacy in coping with cognitive stressors and opioid activation. *Journal of Personality and Social Psychology*, 55(3), 479-488.
- Bandura, A., & Locke, E. A. (2003). Negative self-efficacy and goal effects revisited. *Journal of Applied Psychology*, 88(1), 87-99.
- Bergstrom, K., Carlsson, C. P., Lindholm, C., & Widengren, R. (2000). Improvement of urge- and mixed-type incontinence after acupuncture treatment among elderly women - a pilot study. *Journal of the Autonomic Nervous System*, 79(2-3), 173-180.
- Black, N., Griffiths, J., & Pope, C. (1996). Development of a symptom severity index and a symptom impact index for stress incontinence in women. *Neurourology and Urodynamics*, 15(6), 630-640. doi:10.1002/(SICI)1520-6777(1996)15:6<630::AID-NAU4>3.0.CO;2-G
- Borello-France, D., Burgio, K. L., Goode, P. S., Markland, A. D., Kenton, K., Balasubramanyam, A., . . . Urinary Incontinence Treatment, N. (2010). Adherence to behavioral interventions for urge incontinence when combined with drug therapy: Adherence rates, barriers, and predictors. *Physical Therapy*, 90(10), 1493-1505. doi:10.2522/ptj.20080387
- Boyes, A. (Jan 10, 2013). What is catastrophizing? Cognitive distortions. *Psychology Today*. Retrieved from <https://www.psychologytoday.com/blog/in-practice/201301/what-is-catastrophizing-cognitive-distortions>
- Brubaker, L., Richter, H. E., Visco, A., Mahajan, S., Nygaard, I., Braun, T. M., . . . Weber, A. M. (2008). Refractory idiopathic urge urinary incontinence and botulinum A injection. *The Journal of Urology*, 180(1), 217-222.
- Brown, K. W., & Ryan, R. M. (2003). The benefits of being present: Mindfulness and its role in psychological well-being. *Journal of Personality and Social Psychology*, 84(4), 822-848. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/12703651>
- Burgio, K. L. (2009). Behavioral treatment of urinary incontinence, voiding dysfunction, and overactive bladder. *Obstetrics and Gynecology Clinics of North America*, 36(3), 475-491. Retrieved from <http://www.sciencedirect.com/science/article/pii/S088985450900062X>
- Burgio, K. L., Goode, P. S., Locher, J. L., Umlauf, M. G., Roth, D. L., Richter, H. E., . . . Lloyd, L. K. (2002). Behavioral training with and without biofeedback in the treatment of urge incontinence in older women: A randomized controlled trial.

- Journal of American Medical Association*, 288(18), 2293-2299.
- Burgio, K. L., Goode, P. S., Richter, H. E., Markland, A. D., Johnson, T. M., 2nd, & Redden, D. T. (2010). Combined behavioral and individualized drug therapy versus individualized drug therapy alone for urge urinary incontinence in women. *Journal of Urology*, 184(2), 598-603. doi:10.1016/j.juro.2010.03.141
- Burgio, K. L., Kraus, S. R., Menefee, S., Borello-France, D., Corton, M., Johnson, H. W., . . . Urinary Incontinence Treatment, N. (2008). Behavioral therapy to enable women with urge incontinence to discontinue drug treatment: A randomized trial. *Annals of Internal Medicine*, 149(3), 161-169. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/18678843>
- Cardozo, L. D. (2000). Biofeedback in overactive bladder. *Urology*, 55(5A Suppl), 24-28; discussion 31-22.
- Carroll, D. L. (1995). The importance of self-efficacy expectations in elderly patients recovering from coronary artery bypass surgery. *Heart and Lung*, 24(1), 50-59.
- Chang, L. (2005). Brain responses to visceral and somatic stimuli in irritable bowel syndrome: A central nervous system disorder? *Gastroenterology Clinics of North America*, 34(2), 271-279. doi:10.1016/j.gtc.2005.02.003
- Cherniack, E. P. (2006). Biofeedback and other therapies for the treatment of urinary incontinence in the elderly. *Alternative Medicine Review*, 11(3), 224-231.
- Chiesa, A., & Serretti, A. (2010). A systematic review of neurobiological and clinical features of mindfulness meditations. *Psychological Medicine*, 40(8), 1239-1252. doi:10.1017/S0033291709991747
- Cohen, S., Kamarck, T., & Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior*, 24(4), 385-396. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/6668417>
- Complementary, alternative, or integrative health: What's in a name? (2015). National Center for Complementary and Integrative Health. Bethesda, MD: National Institutes of Health.
- Coyne, K. S., Wein, A. J., Tubaro, A., Sexton, C. C., Thompson, C. L., Kopp, Z. S., & Aiyer, L. P. (2009). The burden of lower urinary tract symptoms: Evaluating the effect of LUTS on health-related quality of life, anxiety and depression: EpiLUTS. *BJU International*, 103 Suppl 3, 4-11. doi:10.1111/j.1464-410X.2009.08371.x
- Coyne, K. S., Zhou, Z., Thompson, C., & Versi, E. (2003). The impact on health-related quality of life of stress, urge and mixed urinary incontinence. *BJU International*, 92(7), 731-735.

- Creswell, J. D., Irwin, M. R., Burklund, L. J., Lieberman, M. D., Arevalo, J. M., Ma, J., . . . Cole, S. W. (2012). Mindfulness-based stress reduction training reduces loneliness and pro-inflammatory gene expression in older adults: A small randomized controlled trial. *Brain, Behavior, and Immunity*, 26(7), 1095-1101.
- del Carmen, M. G., & Rice, L. W. (2015). Underrepresentation of women in clinical trials. *Obstetrics & Gynecology*, 125(3), 616-619.
- Demaagd, G. A., & Davenport, T. C. (2012). Management of urinary incontinence. *Pharmacy and Therapeutics*, 37(6), 345-361H.
- Devlin, G. (2010). Women and elderly: Subgroups under-represented in clinical trials. *Current Opinion in Cardiology*, 25(4), 335-339.
doi:10.1097/HCO.0b013e328338bcab
- Diokno, A. C., Sampselle, C. M., Herzog, A. R., Raghunathan, T. E., Hines, S., Messer, K., . . . Leite, M. C. (2004). Prevention of urinary incontinence by behavioral modification program: A randomized, controlled trial among older women in the community. *Journal of Urology*, 171(3), 1165-1171.
doi:10.1097/01.ju.0000111503.73803.c2
- Dubeau, C. E., Simon, S. E., & Morris, J. N. (2006). The effect of urinary incontinence on quality of life in older nursing home residents. *Journal of the American Geriatric Society*, 54(9), 1325-1333. doi:10.1111/j.1532-5415.2006.00861.x
- Dumoulin, C., & Hay-Smith, J. (2010). Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database of Systematic Reviews*, 1(1), 1-51.
- Elstad, E. A., Maserejian, N. N., McKinlay, J. B., & Tennstedt, S. L. (2011). Fluid manipulation among individuals with lower urinary tract symptoms: A mixed methods study. *Journal of Clinical Nursing*, 20(1-2), 156-165.
doi:10.1111/j.1365-2702.2010.03493.x
- Emmons, S. L., & Otto, L. (2005). Acupuncture for overactive bladder: A randomized controlled trial. *Obstetrics and Gynecology*, 106(1), 138-143.
doi:10.1097/01.AOG.0000163258.57895.ec
- Femia, E. E., Zarit, S. H., & Johansson, B. (1997). Predicting change in activities of daily living: A longitudinal study of the oldest old in Sweden. *The Journals of Gerontology, Series B: Psychological Sciences and Social Sciences*, 52(6), P294-302.
- FitzGerald, M. P., Butler, N., Shott, S., & Brubaker, L. (2002). Bother arising from urinary frequency in women. *Neurology and Urodynamics*, 21(1), 36-40; discussion 41.
- Fjorback, L., Arendt, M., Ørnbøl, E., Fink, P., & Walach, H. (2011). Mindfulness-based

- stress reduction and mindfulness-based cognitive therapy—a systematic review of randomized controlled trials. *Acta Psychiatrica Scandinavica*, 124(2), 102-119. Retrieved from <http://onlinelibrary.wiley.com/store/10.1111/j.1600-0447.2011.01704.x/asset/j.1600-0447.2011.01704.x.pdf?v=1&t=igsgtz8x&s=45b25d6fbe0096a52d84b6a62f32e5a5c1156d07>
- Fortinsky, R. H., Bohannon, R. W., Litt, M. D., Tennen, H., Maljanian, R., Fifield, J., . . . Kenyon, L. (2002). Rehabilitation therapy self-efficacy and functional recovery after hip fracture. *International Journal of Rehabilitation Research*, 25(3), 241-246.
- Fowler, C. J., Griffiths, D., & de Groat, W. C. (2008). The neural control of micturition. *Nature Reviews Neuroscience*, 9(6), 453-466. doi:10.1038/nrn2401
- Franco, I. (2011). The central nervous system and its role in bowel and bladder control. *Current Urology Reports*, 12(2), 153-157. doi:10.1007/s11934-010-0167-8
- Gallegos, A. M., Hoerger, M., Talbot, N. L., Krasner, M. S., Knight, J. M., Moynihan, J. A., & Duberstein, P. R. (2013). Toward identifying the effects of the specific components of mindfulness-based stress reduction on biologic and emotional outcomes among older adults. *The Journal of Alternative and Complementary Medicine*, 19(10), 787-792. Retrieved from <http://online.liebertpub.com/doi/pdfplus/10.1089/acm.2012.0028>
- Garland, E. L., Gaylord, S. A., Palsson, O., Faurot, K., Douglas Mann, J., & Whitehead, W. E. (2012). Therapeutic mechanisms of a mindfulness-based treatment for IBS: Effects on visceral sensitivity, catastrophizing, and affective processing of pain sensations. *Journal of Behavioral Medicine*, 35(6), 591-602. doi:10.1007/s10865-011-9391-z
- Gaugler, J. E., Duval, S., Anderson, K. A., & Kane, R. L. (2007). Predicting nursing home admission in the U.S.: A meta-analysis. *BMC Geriatrics*, 7, 13. doi:10.1186/1471-2318-7-13
- Gaylord, S. A., Whitehead, W. E., Coble, R. S., Faurot, K. R., Palsson, O. S., Garland, E. L., . . . Mann, J. D. (2009). Mindfulness for irritable bowel syndrome: Protocol development for a controlled clinical trial. *BMC Complementary and Alternative Medicine*, 9, 24. doi:10.1186/1472-6882-9-24
- Goode, P. S., Burgio, K. L., Kraus, S. R., Kenton, K., Litman, H. J., Richter, H. E., & Urinary Incontinence Treatment, N. (2011). Correlates and predictors of patient satisfaction with drug therapy and combined drug therapy and behavioral training for urgency urinary incontinence in women. *International Urogynecology Journal*, 22(3), 327-334. doi:10.1007/s00192-010-1287-x
- Gopal, M., Haynes, K., Bellamy, S. L., & Arya, L. A. (2008). Discontinuation rates of anticholinergic medications used for the treatment of lower urinary tract

- symptoms. *Obstetrics & Gynecology*, 112(6), 1311-1318.
doi:10.1097/AOG.0b013e31818e8aa4
- Griffiths, D., & Tadic, S. D. (2008). Bladder control, urgency, and urge incontinence: Evidence from functional brain imaging. *Neuourology and Urodynamics*, 27(6), 466-474. doi:10.1002/nau.20549
- Griffiths, D., Tadic, S. D., Schaefer, W., & Resnick, N. M. (2007). Cerebral control of the bladder in normal and urge-incontinent women. *Neuroimage*, 37(1), 1-7. doi:10.1016/j.neuroimage.2007.04.061
- Grossman, P., Niemann, L., Schmidt, S., & Walach, H. (2004). Mindfulness-based stress reduction and health benefits. A meta-analysis. *Journal of Psychosomatic Research*, 57(1), 35-43. doi:10.1016/S0022-3999(03)00573-7.
- Hanley, J., Capewell, A., & Hagen, S. (2001). Validity study of the severity index, a simple measure of urinary incontinence in women. *BMJ*, 322(7294), 1096-1097.
- Hannestad, Y. S., Rortveit, G., Sandvik, H., Hunskaar, S., & Norwegian, E. S. E. O. I. I. T. C. O. N.-T. (2000). A community-based epidemiological survey of female urinary incontinence: The Norwegian EPINCONT study. Epidemiology of Incontinence in the County of Nord-Trondelag. *Journal of Clinical Epidemiology*, 53(11), 1150-1157.
- Hartmann, K. E., McPheeters, M. L., Biller, D. H., Ward, R. M., McKoy, J. N., Jerome, R. N., . . . Blume, J. D. (2009). Treatment of overactive bladder in women. *Evidence Report Technology Assessment (Full Report)*(187), 1-120, v. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/19947666>
- Hersh, L., & Salzman, B. (2013). Clinical management of urinary incontinence in women. *American Family Physician*, 87(9), 634-640.
- Holzel, B. K., Ott, U., Hempel, H., Hackl, A., Wolf, K., Stark, R., & Vaitl, D. (2007). Differential engagement of anterior cingulate and adjacent medial frontal cortex in adept meditators and non-meditators. *Neuroscience Letters*, 421(1), 16-21. doi:10.1016/j.neulet.2007.04.074
- Huang, A. J., Jenny, H. E., Chesney, M. A., Schembri, M., & Subak, L. L. (2014). A group-based yoga therapy intervention for urinary incontinence in women: A pilot randomized trial. *Female Pelvic Medicine and Reconstructive Surgery*, 20(3), 147-154. doi:10.1097/SPV.0000000000000072
- Hubeaux, K., Deffieux, X., Ismael, S. S., Raibaut, P., & Amarenco, G. (2007). Autonomic nervous system activity during bladder filling assessed by heart rate variability analysis in women with idiopathic overactive bladder syndrome or stress urinary incontinence. *Journal of Urology*, 178(6), 2483-2487. doi:10.1016/j.juro.2007.08.036

- Hubeaux, K., Deffieux, X., Raibaut, P., Le Breton, F., Jousse, M., & Amarenco, G. (2011). Evidence for autonomic nervous system dysfunction in females with idiopathic overactive bladder syndrome. *Neurourology and Urodynamics*, 30(8), 1467-1472. doi:10.1002/nau.21154
- Im, H. W., Kim, M. D., Kim, J. C., & Choi, J. B. (2010). Autonomous nervous system activity in women with detrusor overactivity. *Korean Journal of Urology*, 51(3), 183-186. doi:10.4111/kju.2010.51.3.183
- Jha, A. P., Krompinger, J., & Baime, M. J. (2007). Mindfulness training modifies subsystems of attention. *Cognitive, Affective, & Behavioral Neuroscience*, 7(2), 109-119. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/17672382>
- Kabat-Zinn, J. (2003). Mindfulness-based stress reduction (MBSR). *Constructivism in the Human Sciences*.
- Kabat-Zinn, J. (2005). Bringing mindfulness to medicine: An interview with Jon Kabat-Zinn, PhD. Interview by Karolyn Gazella. *Advances in Mind-Body Medicine*, 21(2), 22-27.
- Karsenty, G., Denys, P., Amarenco, G., De Seze, M., Game, X., Haab, F., . . . Chartier-Kastler, E. (2008). Botulinum toxin A (Botox) intradetrusor injections in adults with neurogenic detrusor overactivity/neurogenic overactive bladder: A systematic literature review. *European Urology*, 53(2), 275-287. doi:10.1016/j.eururo.2007.10.013
- Kelleher, C. J., Cardozo, L. D., Khullar, V., & Salvatore, S. (1997). A medium-term analysis of the subjective efficacy of treatment for women with detrusor instability and low bladder compliance. *British Journal of Obstetrics and Gynaecology*, 104(9), 988-993.
- Kienle, G. S., Albonico, H. U., Fischer, L., Frei-Erb, M., Hamre, H. J., Heusser, P., . . . Kiene, H. (2011). Complementary therapy systems and their integrative evaluation. *Explore (NY)*, 7(3), 175-187. doi:10.1016/j.explore.2011.02.001
- Kilpatrick, L. A., Suyenobu, B. Y., Smith, S. R., Bueller, J. A., Goodman, T., Creswell, J. D., . . . Naliboff, B. D. (2011). Impact of mindfulness-based stress reduction training on intrinsic brain connectivity. *Neuroimage*, 56(1), 290-298. doi:10.1016/j.neuroimage.2011.02.034
- Klovning, A., Avery, K., Sandvik, H., & Hunskaar, S. (2009). Comparison of two questionnaires for assessing the severity of urinary incontinence: The ICIQ-UI SF versus the incontinence severity index. *Neurourology and Urodynamics*, 28(5), 411-415. doi:10.1002/nau.20674
- Kwak, Y., Kwon, H., & Kim, Y. (2015). Health-related quality of life and mental health in older women with urinary incontinence. *Aging & Mental Health*, 1-8. doi:10.1080/13607863.2015.1033682

- Lai, H., Gardner, V., Vetter, J., & Andriole, G. L. (2015). Correlation between psychological stress levels and the severity of overactive bladder symptoms. *BMC Urology*, 15(1). doi:10.1186/s12894-015-0009-6
- Lenze, E. J., Hickman, S., Hershey T, Wendleton, L., Ly, K., Dixon, D., Dore, P., Wetherell, J.L. (2014). Mindfulness-based stress reduction for older adults with worry symptoms and co-occurring cognitive dysfunction. *International Journal of Geriatric Psychiatry*, 29(10), 991-1000.
- Loera, J. A., Black, S. A., Markides, K. S., Espino, D. V., & Goodwin, J. S. (2001). The use of herbal medicine by older Mexican Americans. *Journals of Gerontology. Series A: Biological Sciences and Medical Sciences*, 56(11), M714-718.
- MacCoon, D. G., Imel, Z. E., Rosenkranz, M. A., Sheftel, J. G., Weng, H. Y., Sullivan, J. C., . . . Lutz, A. (2012). The validation of an active control intervention for mindfulness based stress reduction (MBSR). *Behaviour Research and Therapy*, 50(1), 3-12. doi:10.1016/j.brat.2011.10.011
- Mannesse, C. K., Derkx, F., De Ridder, M., & van der Cammen, T. (2000). Contribution of adverse drug reactions to hospital admission of older patients. *Age and Ageing*, 29(1), 35-39. Retrieved from <http://ageing.oxfordjournals.org/content/29/1/35.full.pdf>
- Markland, A. D., Richter, H. E., Fwu, C. W., Eggers, P., & Kusek, J. W. (2011). Prevalence and trends of urinary incontinence in adults in the United States, 2001 to 2008. *Journal of Urology*, 186(2), 589-593. doi:10.1016/j.juro.2011.03.114
- McEwen, B. S., & Gianaros, P. J. (2010). Central role of the brain in stress and adaptation: Links to socioeconomic status, health, and disease. *Annals of the New York Academy of Sciences*, 1186(1), 190-222.
- Melville, J. L., Katon, W., Delaney, K., & Newton, K. (2005). Urinary incontinence in US women: A population-based study. *Archives of Internal Medicine*, 165(5), 537-542. doi:10.1001/archinte.165.5.537
- Milne, J. L. (2008). Behavioral therapies for overactive bladder: Making sense of the evidence. *Journal of Wound Ostomy & Continence Nursing*, 35(1), 93-101.
- Morone, N. E., Greco, C. M., & Weiner, D. K. (2008). Mindfulness meditation for the treatment of chronic low back pain in older adults: A randomized controlled pilot study. *Pain*, 134(3), 310-319. doi:10.1016/j.pain.2007.04.038
- Morrison, A., & Levy, R. (2006). Fraction of nursing home admissions attributable to urinary incontinence. *Value in Health*, 9(4), 272-274. doi:10.1111/j.1524-4733.2006.00109.x
- Moss, A. S., Reibel, D. K., Greeson, J. M., Thapar, A., Bubb, R., Salmon, J., & Newberg, A. B. (2015). An adapted mindfulness-based stress reduction program for elders

- in a continuing care retirement community: Quantitative and qualitative results from a pilot randomized controlled trial. *Journal of Applied Gerontology*, 34(4), 518-538. doi:10.1177/0733464814559411
- Moynihan, J. A., Chapman, B. P., Klorman, R., Krasner, M. S., Duberstein, P. R., Brown, K. W., & Talbot, N. L. (2013). Mindfulness-based stress reduction for older adults: Effects on executive function, frontal alpha asymmetry and immune function. *Neuropsychobiology*, 68(1), 34-43. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3831656/pdf/nihms-523229.pdf>
- Murphy, M., Culligan, P. J., Arce, C. M., Graham, C. A., Blackwell, L., & Heit, M. H. (2006). Construct validity of the incontinence severity index. *Neurourology and Urodynamics*, 25(5), 418-423. doi:10.1002/nau.20246
- Nabi, G., Cody, J. D., Ellis, G., Herbison, P., & Hay-Smith, J. (2006). Anticholinergic drugs versus placebo for overactive bladder syndrome in adults. *Cochrane Database of Systematic Reviews* (4), CD003781. doi:10.1002/14651858.CD003781.pub2
- Nahin, R. L., Dahlhamer, J. M., Taylor, B. L., Barnes, P. M., Stussman, B. J., Simile, C. M., . . . McFann, K. K. (2007). Health behaviors and risk factors in those who use complementary and alternative medicine. *BMC Public Health*, 7, 217. doi:10.1186/1471-2458-7-217
- Oh, S. J., & Ku, J. H. (2007). Impact of self-perceived bothersomeness on health-related quality of life in women with overactive bladder symptoms. *Urologia Internationalis*, 78(1), 63-69. doi:10.1159/000096937
- Paik, S. H., Han, S. R., Kwon, O. J., Ahn, Y. M., Lee, B. C., & Ahn, S. Y. (2013). Acupuncture for the treatment of urinary incontinence: A review of randomized controlled trials. *Experimental and Therapeutic Medicine*, 6(3), 773-780. doi:10.3892/etm.2013.1210
- Palta, P., Page, G., Piferi, R., Gill, J., Hayat, M., Connolly, A., & Szanton, S. (2012). Evaluation of a mindfulness-based intervention program to decrease blood pressure in low-income African-American older adults. *Journal of Urban Health*, 89(2), 308-316.
- Pearlin, L. I., Lieberman, M. A., Menaghan, E. G., & Mullan, J. T. (1981). The stress process. *Journal of Health and Social Behavior*, 22(4), 337-356.
- Pearlin, L. I., Schieman, S., Fazio, E. M., & Meersman, S. C. (2005). Stress, health, and the life course: Some conceptual perspectives. *Journal of Health and Social Behavior*, 46(2), 205-219.
- Penson, D. F. (2013). Re: Effect of bothersome overactive bladder symptoms on health-related quality of life, anxiety, depression, and treatment seeking in the United States: Results from EpiLUTS. *Journal of Urology*, 189(3), 1001.

doi:10.1016/j.juro.2012.11.129

- Petrou, S. P., Parker, A. S., Crook, J. E., Rogers, A., Metz-Kudashick, D., & Thiel, D. D. (2009). Botulinum a toxin/dimethyl sulfoxide bladder instillations for women with refractory idiopathic detrusor overactivity: A phase 1/2 study. *Mayo Clinic Proceedings*, 84(8), 702-706. doi:10.1016/S0025-6196(11)60520-X
- Samuelson, M., Carmody, J., Kabat-Zinn, J., and Bratt, M. (2007). Mindfulness-based stress reduction in Massachusetts correctional facilities. *The Prison Journal*, 87, 254-268.
- Schmidt, R. A., Jonas, U., Oleson, K. A., Janknegt, R. A., Hassouna, M. M., Siegel, S. W., & van Kerrebroeck, P. E. (1999). Sacral nerve stimulation for treatment of refractory urge urinary incontinence. Sacral Nerve Stimulation Study Group. *Journal of Urology*, 162(2), 352-357.
- Segal, Z. V., Williams, J. M. G., & Teasdale, J. D. (2013). *Mindfulness-based cognitive therapy for depression*. New York: Guilford Press.
- Sexton, C. C., Coyne, K. S., Thompson, C., Bavendam, T., Chen, C. I., & Markland, A. (2011). Prevalence and effect on health-related quality of life of overactive bladder in older Americans: Results from the epidemiology of lower urinary tract symptoms study. *Journal of the American Geriatrics Society*, 59(8), 1465-1470. doi:10.1111/j.1532-5415.2011.03492.x
- Shamliyan, T. A., Kane, R. L., Wyman, J., & Wilt, T. J. (2008). Systematic review: Randomized, controlled trials of nonsurgical treatments for urinary incontinence in women. *Annals of Internal Medicine*, 148(6), 459-473.
- Shepherd, J. P., Lowder, J. L., Leng, W. W., & Smith, K. J. (2011). InterStim sacral neuromodulation and Botox botulinum-A toxin intradetrusor injections for refractory urge urinary incontinence: A decision analysis comparing outcomes including efficacy and complications. *Female Pelvic Medicine & Reconstructive Surgery*, 17(4), 199-203. doi:10.1097/SPV.0b013e318224e0d7
- Siegel, S. W., Catanzaro, F., Dijkema, H. E., Elhilali, M. M., Fowler, C. J., Gajewski, J. B., . . . Schmidt, R. A. (2000). Long-term results of a multicenter study on sacral nerve stimulation for treatment of urge urinary incontinence, urgency-frequency, and retention. *Urology*, 56(6), 87-91.
- Simpson, J. A., Weiner, E. S. C., & Oxford University, P. (1989). *The Oxford English Dictionary*. Oxford: Clarendon Press; Oxford University Press.
- Srikrishna, S., Robinson, D., & Cardozo, L. (2010). Validation of the Patient Global Impression of Improvement (PGI-I) for urogenital prolapse. *International Urogynecology Journal*, 21(5), 523-528. doi:10.1007/s00192-009-1069-5
- Subak, L. L., Wing, R., West, D. S., Franklin, F., Vittinghoff, E., Creasman, J. M., . . .

- Investigators, P. (2009). Weight loss to treat urinary incontinence in overweight and obese women. *New England Journal of Medicine*, 360(5), 481-490. doi:10.1056/NEJMoa0806375
- Szanton, S. L., Wenzel, J., Connolly, A. B., & Piferi, R. L. (2011). Examining mindfulness-based stress reduction: Perceptions from minority older adults residing in a low-income housing facility. *BMC Complementary and Alternative Medicine*, 11(1), 44. Retrieved from <http://www.biomedcentral.com/content/pdf/1472-6882-11-44.pdf>
- Tang, D. H., Colayco, D. C., Khalaf, K. M., Piercy, J., Patel, V., Globe, D., & Ginsberg, D. (2014). Impact of urinary incontinence on healthcare resource utilization, health-related quality of life and productivity in patients with overactive bladder. *BJU International*, 113(3), 484-491. doi:10.1111/bju.12505
- Tenfelde, S., & Janusek, L. W. (2014). Yoga: A biobehavioral approach to reduce symptom distress in women with urge urinary incontinence. *Journal of Alternative and Complementary Medicine*, 20(10), 737-742. doi:10.1089/acm.2013.0308
- Thoits, P. A. (2010). Stress and health major findings and policy implications. *Journal of Health and Social Behavior*, 51(1 suppl), S41-S53.
- Tinetti, M. E., Mendes de Leon, C. F., Doucette, J. T., & Baker, D. I. (1994). Fear of falling and fall-related efficacy in relationship to functioning among community-living elders. *Journal of Gerontology*, 49(3), M140-147.
- Turner, R. J. (2010). Understanding health disparities: The promise of the stress process model. In W. R. Avison, C. S., Aneshensel, S. Schieman, & B. Wheaton (Eds.) *Advances in the conceptualization of the stress process* (pp. 3-21): Switzerland: Springer.
- van der Vaart, C. H., de Leeuw, J. R., Roovers, J. P., & Heintz, A. P. (2002). The effect of urinary incontinence and overactive bladder symptoms on quality of life in young women. *BJU International*, 90(6), 544-549.
- Visco, A. G., Brubaker, L., Richter, H. E., Nygaard, I., Paraiso, M. F., Menefee, S. A., . . . Pelvic Floor Disorders, N. (2012a). Anticholinergic therapy vs. onabotulinumtoxin for urgency urinary incontinence. *New England Journal of Medicine*, 367(19), 1803-1813. doi:10.1056/NEJMoa1208872
- Visco, A. G., Brubaker, L., Richter, H. E., Nygaard, I., Paraiso, M. F., Menefee, S. A., . . . Pelvic Floor Disorders, N. (2012b). Anticholinergic versus botulinum toxin A comparison trial for the treatment of bothersome urge urinary incontinence: ABC trial. *Contemporary Clinical Trials*, 33(1), 184-196. doi:10.1016/j.cct.2011.09.019
- Wang, A. C. (2000). Bladder-sphincter biofeedback as treatment of detrusor instability in

- women who failed to respond to oxybutynin. *Chang Gung Medical Journal*, 23(10), 590-599.
- Wang, A. C., Wang, Y. Y., & Chen, M. C. (2004). Single-blind, randomized trial of pelvic floor muscle training, biofeedback-assisted pelvic floor muscle training, and electrical stimulation in the management of overactive bladder. *Urology*, 63(1), 61-66.
- Watson, D., Clark, L. A., & Tellegen, A. (1988). Development and validation of brief measures of positive and negative affect: The PANAS scales. *Journal of Personality and Social Psychology*, 54, 1063–1070
- Wing, R. R., West, D. S., Grady, D., Creasman, J. M., Richter, H. E., Myers, D., . . . Exercise, G. (2010). Effect of weight loss on urinary incontinence in overweight and obese women: Results at 12 and 18 months. *Journal of Urology*, 184(3), 1005-1010. doi:10.1016/j.juro.2010.05.031
- Wyman, J., Burgio, K., & Newman, D. (2009). Practical aspects of lifestyle modifications and behavioural interventions in the treatment of overactive bladder and urgency urinary incontinence. *International Journal of Clinical Practice*, 63(8), 1177-1191. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2734927/pdf/ijcp0063-1177.pdf>
- Wyman, J. F., Harding, G., Klutke, C., Burgio, K., Berriman, S., Vats, V., . . . Coyne, K. S. (2010). Contributors to satisfaction with combined drug and behavioral therapy for overactive bladder in subjects dissatisfied with prior drug treatment. *Journal of Wound Ostomy and Continence Nursing*, 37(2), 199-205. doi:10.1097/WON.0b013e3181cf722f
- Wyman, J. F., Klutke, C., Burgio, K., Guan, Z., Sun, F., Berriman, S., & Bavendam, T. (2010). Effects of combined behavioral intervention and tolterodine on patient-reported outcomes. *The Canadian Journal of Urology*, 17(4), 5283-5290.
- Young, L. A., & Baime, M. J. (2010). Mindfulness-based stress reduction: Effect on emotional distress in older adults. *Complementary Health Practice Review*, 15(2), 59-64.

CHAPTER 3

USING MINDFULNESS APPROACHES TO TREAT URGE URINARY INCONTINENCE IN OLDER ADULT WOMEN: A LITERATURE REVIEW

Katarina Friberg Felsted
Katherine P. Supiano

Conflict of Interest: None

Disclosure of funding received: University of Utah College of Nursing Noorda-Hartford Fellowship, the University of Utah Office of the Associate Vice President for Health Equity and Inclusion, and the Sigma Theta Tau International Gamma Rho Chapter

3.1 Abstract

We examined the research literature to evaluate evidence of mindfulness approaches to treat urge urinary incontinence in older adult women. Older adult women with urge urinary incontinence are not sufficiently treated with current practices, yet the potential application of mindfulness-based stress reduction to urge urinary incontinence is relatively unknown.

A literature review was conducted to locate scientific literature using mindfulness to treat urinary incontinence in older adult women. No studies examined mindfulness for urinary incontinence specifically in an older adult female, or older adult, population. No mixed gender studies, nor studies only on men, with mindfulness as treatment of urinary incontinence were discovered.

Two studies met the expanded inclusion criteria of mindfulness as a treatment for urinary incontinence in adults (not specifically older adults). Both demonstrated that mindfulness-based stress reduction reduced urge urinary incontinence symptoms and increased health-related quality of life and global impression of improvement after completion of the intervention and at follow-up.

Mindfulness-based stress reduction remains a novel approach. Preliminary research indicates mindfulness-based stress reduction works in the general population to reduce urge urinary incontinence, but has not been examined in large clinical trials, or in special populations such as adults 65 and older.

3.2 Introduction

Urinary incontinence is a lower urinary tract syndrome defined as the inability to hold urine in the bladder because voluntary control is lost, resulting in involuntary leakage 3). Urge urinary incontinence disproportionately affects older women and adversely affects health related quality of life (Coyne, Sexton, et al., 2008; Nitti, 2001). Urge urinary incontinence (UUI) in older adult women is a distressing problem needing innovative solutions.

3.3 Background

Historically, urge urinary incontinence has been understood to be related to bladder dysfunction, poor muscle tone in the pelvic floor, obesity, nerve dysfunction, or a combination of these (Andersson, 2002; Fowler, Griffiths, & de Groat, 2008; Griffiths, Tadic, Schaefer, & Resnick, 2007; Subak et al., 2009). While these causes may explain some urge urinary incontinence, they do not account for all cases. In reality, most urge urinary incontinence is idiopathic (Qaseem et al., 2014).

The decreasing efficacy of pharmacologic treatment and the tendency for women with urge urinary incontinence to require multicomponent behavioral therapy indicate a need for more effective treatment options (Hartmann et al., 2009; Tenfelde & Janusek, 2014). Recent research suggests that urge urinary incontinence may be due to abnormal function within the brain, rather than within the nervous system or bladder (Baker, Costa, Guarino, & Nygaard, 2014; Baker, Costa, & Nygaard, 2012). Women with urge urinary incontinence present with an autonomic nervous system imbalance while women with stress urinary incontinence retain autonomic nervous system balance

(Hubeaux et al., 2011; Im, Kim, Kim, & Choi, 2010). Tenfelde and Janusek discussed the possibility that meditative approaches may correct this autonomic nervous system imbalance in women with urge urinary incontinence (Tenfelde & Janusek, 2014).

Preliminary research on mindfulness-based stress reduction (MBSR) to treat chronic conditions has been shown to regulate visceral awareness and improve self-regulation (Tenfelde & Janusek, 2014). Mindfulness-based stress reduction has been proven a useful intervention for a “broad range of chronic disorders and problems” (Grossman, Niemann, Schmidt, & Walach, 2004). As such, it could be an intriguing integrative treatment for urge urinary incontinence, as urge urinary incontinence often proves refractory to common treatments (Hartmann et al., 2009). Older adult women with urge urinary incontinence are not sufficiently treated with current practices, yet little is known about the potential application of MBSR to UUI.

3.4 Methods

A literature review was conducted to determine if mindfulness-based stress reduction has been studied on the urge urinary incontinent older adult female population. The scope of this review included mindfulness interventions on older adult women with urinary incontinence. It was subsequently broadened to include all adults without specificity in age or gender.

3.4.1 Search Strategy

3.4.1.1 Databases

The literature review was performed using the following electronic research databases: Academic Search Premier, AgeLine, Alternative Health Watch, Biomedical Reference Collection, CINAHL, Embase, ERIC, Fuente Academica, Funk & Wagnall's New World Encyclopedia, GreenFILE, Health Source: Consumer Edition, Health Source: Nursing/Academic Edition, Legal Collection, Library, Information Science & Technology Abstracts, MedicLatina, MEDLINE, Military & Government Collection, MLA Directory of Periodicals, MLA International Bibliography, Professional Development Collection, PsycARTICLES, Psychology and Behavioral Sciences Collection, PsychINFO®, PubMed, Regional Business News, Scopus, and TOPICsearch to locate relevant literature.

3.4.1.2 Inclusion and Exclusion Criteria

Inclusion criteria for this search were psychosocial/nonpharmacologic clinical trials and randomized controlled trials for older adults with urinary incontinence. Exclusion criteria were theory articles, studies that were diagnostic or addressing incidence and prevalence, opinion pieces, and articles that were not in English and had no translation available. Also excluded were studies with children as participants, studies with cancer patients or participants who were identified as cancer survivors, and studies on fecal incontinence.

3.4.1.3 Terms

An initial search using the keywords *urinary incontinence*, *mindfulness*, and *older adults* produced one result (Baker, Costa, Guarino, & Nygaard, 2014). Thus, search terms were significantly broadened to include the following phrases: *urge urinary incontinence*, *urinary incontinence*, *incontinence*, *mindfulness-based stress reduction*, *mindfulness training*, *mindfulness intervention*, *psychosocial interventions*, *older adults*, *elderly*, *older adult women*, *older adult females*, *complementary therapy/ies*, and *alternative therapy/ies*. Searches were systematically carried out within each database, using the same combination of terms in the same order. In certain databases, such as Scopus, it was necessary to add quotation marks around compound terms. Additional literature was located through a thorough search of the references within the articles identified, as well as through other sources.

3.4.1.4 Search Results

Ninety-one records were identified, 18 were duplicates, and 71 of the remaining 73 were deemed irrelevant after a thorough review of the title and abstract (see Figure 1). Studies on fecal incontinence; children; participants with, or who were survivors of, cancer; editorial views; theoretical articles; and articles in foreign languages were systematically excluded from review. No studies examined mindfulness as treatment for urinary incontinence specifically in an older adult female, or older adult, population. One explicitly stated at least one older adult woman was involved, while the other study's oldest participant was 60 years old. Both of these studies limited recruitment to women only. No mixed gender studies, nor studies only on men, with mindfulness as

treatment of urinary incontinence were discovered in the literature review. Thus, two studies met the broadened inclusion criteria of mindfulness as a treatment for urinary incontinence in adults (not specifically older adult women).

3.4.1.5 Grey Literature

In addition to the systematic search of databases described above, a review of the grey literature was conducted. ProQuest Digital Dissertations was searched. The last 4 years of conference proceedings from three organizations, representing each facet of the topic (complementary approaches, urge urinary incontinence, older adults) were also searched. The Academy of Integrative Health and Medicine's 2014, 2015, and 2016 conferences were searched and revealed no presentations about using mindfulness-based stress reduction to treat urge urinary incontinence in older adult women. The Academy did not hold a 2013 conference. To be most inclusive, the search was broadened to mindfulness and urinary incontinence and this still yielded zero results. This was continued with the conference proceedings of the remaining two organizations chosen.

The American Urogynecologic Society's 2013, 2014, 2015, and 2016 conference proceedings were searched and one presentation each year met the search criteria. The 2013 presentation, "Mindfulness-Based Stress Reduction (MBSR) vs Yoga on Urgency Incontinence: A Randomized Pilot Study" is a precursor to the Baker article discussed below (Baker, Costa, Guarino, & Nygaard, 2014). The 2014, 2015, and 2016 conferences each had one presentation or participation in a Roundtable Discussion (alternately entitled Meet the Experts Educational Roundtables) by Baker, each entitled

“Mindfulness for Urinary Urge Incontinence.” Ms. Baker has not published related to this topic since 2014.

The Gerontological Society of America’s 2013, 2014, 2015, and 2016 conference proceedings were searched and no presentations met the criteria, even when broadened to simply mindfulness and urinary incontinence.

3.5 Results

Two studies met the broadened criteria of the literature review. Both studies using mindfulness-based stress reduction as a treatment for urge urinary incontinence saw significant reduction in the urinary incontinence episodes and overactive bladder symptoms of its participants after completion of an 8-week mindfulness-based stress reduction course, as well as increases in health related quality of life and global impression of improvement (Baker et al., 2014; Baker, Costa, & Nygaard, 2012).

3.5.1 Synthesis of Literature

Continued positive change, while equivocally statistically significant, was observed at 6-month and 1-year follow-ups. It is worth noting as a potential limitation that these studies were both conducted by research teams with almost identical members, and participants were recruited from the same community with the same recruitment strategies. The later study used yoga as the comparison condition, but technically it was not yoga, as emphasis was placed on physical movement and no education was given on breathing techniques or meditative methods. These are both traditionally an integrative part of yoga practice (Baker et al., 2014). Both studies were

published in the same journal, *Female Pelvic and Reconstructive Surgery*, which has an impact factor of 1.331.

A summary of the study characteristics (participants, methods, interventions, follow-up, and results) and outcome measures (scales used, statistics, allocation, and the like) of both studies are found in Tables 1 and 2, respectively.

3.5.2 Individual Article Summaries

3.5.2.1 Mindfulness-Based Stress Reduction for Treatment of

Urinary Urge Incontinence: A Pilot Study

This pilot study by Baker, Costa, and Nygaard was the first study to examine mindfulness-based stress reduction as a treatment for urge urinary incontinence (Baker et al., 2012). This was a single-armed study, as is typical for a pilot study. Treatment response was measured with 3-day voiding diaries, the Overactive Bladder Symptoms and Quality of Life-Short Form, Health-Related Quality of Life, and Patient Global Impression of Improvement. Seven women were enrolled, a small sample size. However, researchers sought seven participants to meet a power of 80% and an alpha of 0.05. The mean age was 54.9, with participants ranging in age from 43 to 60. The mean body mass index of participants was 28.4. This is noteworthy, since weight has been shown to affect urinary incontinence (Subak et al., 2009; Wing et al., 2010).

Study findings were conclusive: After an 8-week mindfulness-based stress reduction intervention, incontinence episodes per day were reduced by 2.91 ($p = .0005$), a larger decrease than has been seen with cognitive behavioral therapy or pharmacologic treatment (Alhasso, McKinlay, Patrick, & Stewart, 2006; Hartmann et

al., 2009; Mannesse, Derkx, De Ridder, & van der Cammen, 2000). Significant improvements were also observed on the Overactive Bladder Symptoms and Quality of Life-Short Form, the Health-Related Quality of Life, and the Patient Global Impression of Improvement. At the 6-month follow-up, two women had sought additional treatment, but these significant results were sustained in the five remaining participants. At 1 year, one additional participant was lost to follow-up, but the significant results were sustained after 1 year in the remaining four participants. The authors note that the voiding diary may have added therapeutic value, and that the mindfulness-based stress reduction intervention is a labor-intensive treatment.

3.5.2.2 Comparison of Mindfulness-Based Stress Reduction Versus Yoga

on Urinary Urge Incontinence: A Randomized Pilot Study.

With 6-Month and 1-Year Follow-up Visits

This study by Baker, Costa, Guarino, and Nygaard is the first randomized study observing a mindfulness-based stress reduction intervention versus a comparison condition as treatment for urge urinary incontinence in adults (Baker et al., 2014). The study measured the percent change of urinary incontinence episodes between a mindfulness-based stress reduction (intervention) condition and a yoga (comparison) condition. The primary outcome was percent change in urinary incontinence leakage episodes, as recorded in the 3-day voiding diaries. Treatment response was also measured by percent change in the Overactive Bladder Symptoms and Quality of Life-Short Form, the Health-Related Quality of Life scale, and the Patient Global Impression of Improvement. Twenty-four (13 MBSR, 11 yoga) of the original 30 (15 MBSR, 15

yoga) participants completed the majority of classes, 21 (12 MBSR, 9 yoga) completed the 6-month follow-up, and 20 (10 MBSR, 10 yoga) completed the 1-year follow-up. Researchers sought a range of 20–36 women to satisfy a two-tailed analysis with a power of 80% and an alpha of 0.05. A p value of $<.05$ was considered a statistically significant result. Block randomization was utilized to divide the participants into conditions. The participants were all community-dwelling women between the ages of 22 and 79 (no mean age is provided), with urge-predominant urinary incontinence. Out of the 30 total participants, there were 9 women aged 65 and older enrolled in the study (J. Baker, personal communication, 2 November 2015). The comparison condition participated in a yoga program, structured after the Health Enhancement Program (HEP). HEP is designed to mimic the time and social engagement of the mindfulness-based stress reduction classes (MacCoon et al., 2012). Each condition received a total of eight classes. It is important to note that neither condition received any bladder or behavioral education for urge urinary incontinence. The MBSR instructor had completed 14 days of professional training and an advanced teacher training intensive in mindfulness-based cognitive therapy (MBCT). The yoga courses mimicked the MBSR courses in class time and home practice of yoga.

Findings indicated statistically significant drops in urinary incontinence leakage episodes at the 8-week and 6-month mark for those in the MBSR condition. At the 1-year follow-up, episodes were further reduced in the MBSR condition compared to the yoga condition, but where differences were not statistically significant. Further, the MBSR participants scored higher on the Overactive Bladder Symptoms and Quality of Life-Short Form, the Health-Related Quality of Life scale, and the Patient Global

Impression of Improvement at all three time points (8-week, 6-month, and 1-year follow-ups) but results were only statistically significant at the 8-week mark.

3.6 Discussion

The women in these two studies (Baker, Costa, Guarino, & Nygaard, 2014; Baker, Costa, & Nygaard, 2012) may not represent the average woman with urge urinary incontinence since they responded to advertisements of the studies, and it was evident that the interventions would be complementary or integrative. Authors conclude that these results support larger-scale trials to evaluate mindfulness-based stress reduction. Additionally, these results also support trials in specific populations, such as older adult women.

While mindfulness-based stress reduction has been applied in two pilot studies to treat urge urinary incontinence, no research has been done specifically in the older adult population. The two relevant studies both showed that mindfulness-based stress reduction was successful in reducing urge urinary incontinence severity (number of leakage episodes). The studies also showed that participants rated their overactive bladder symptoms lower, and their health related quality of life and global impression of improvement higher after completion of the intervention, and even at a later follow-up time (Baker, Costa, Guarino, & Nygaard, 2014; Baker, Costa, & Nygaard, 2012).

3.7 Conclusion

The highest prevalence of urge urinary incontinence occurs in the population of older adult women (Markland, 2011). Given the underrepresentation of older women in

research studies, and the frequency of and distress associated with UUI, older women are a particularly important population to study (Devlin, 2010). Mindfulness-based stress reduction remains a novel approach within the scientific literature and research on its utility in older women with UUI is a pressing need. There is evidence that mindfulness-based stress reduction works in the general population to reduce urinary incontinence, but this has not been proven in large clinical trials, or in special populations like adults 65 and older. If MBSR proves effective in the urge urinary incontinent older adult female population, its implementation could impact quality of life and independence in affected women. It could also be an efficacious alternative to medications, whose side effects are disproportionately dangerous in the older adult female population (Franco, 2011; Mannesse et al., 2000). Benefits may extrapolate to the population at large, reducing not only personal but societal cost, and improving wellbeing (Ganz et al., 2010; Milsom et al., 2014; Onukwugha et al., 2009).

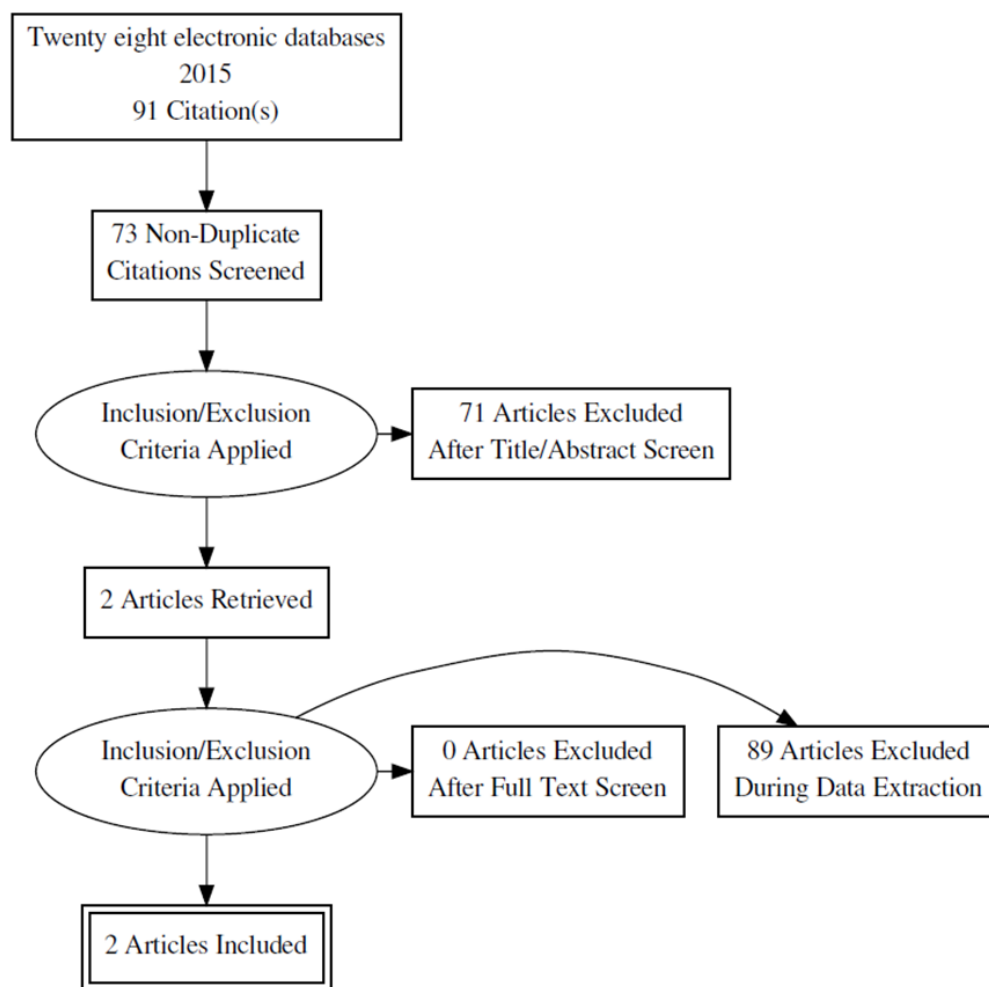


Figure 1 PRISMA Flow Chart of Literature Review Search Results.

Table 1 Study Characteristics

	Baker, J., Costa, D., Guarino, J. M., & Nygaard, I. (2014)	Baker, J., Costa, D., & Nygaard, I. (2012)
Participants	<p>$n = 30$ enrollees,</p> <p>≥ 18 years (22-79 years)</p> <p>White</p> <p>$n = 24$ completed intervention</p>	$n = 7$ enrollees
Intervention	Randomized MBSR or yoga	Single-arm pilot study
Follow-up	<p>$n = 20$ 6-month follow-up visit</p> <p>$n = 21$ 1-year follow-up visit</p>	1-year follow-up data
Results	<p>Median percent change from baseline Overactive Bladder Symptom and Quality of Life Short Form and the Health-Related Quality of Life greater at each time point for MBSR than for yoga; statistically significant only at 8 weeks ($P = .003$ and $.02$, respectively).</p> <p>At 8 weeks, 6/13 MBSR and 0/11 yoga reported “very much better” or “much better” ($p = .02$)</p> <p>At 1 year, 6/12 MBSR and 1/9 yoga reported “very much better” or “much better” ($p = .16$).</p>	<p>UIEs/day decreased from 4.14 at baseline to 1.23 after treatment ($p = .0005$)</p> <p>At study completion of 8-week treatment, 5 of 7 women were improved on the Patient Global Impression of Improvement, and 2 were unchanged. The PGI-I showed sustained or continued improvement</p> <p>Significant improvements on both Overactive Bladder Symptom and Quality of Life-Short Form Health-Related Quality of Life were reported at study completion.</p> <p>PGI-I results were sustained at 1 year in 4 of 7 women.</p>

Table 2 Outcome Measures

	Baker, J., Costa, D., Guarino, J. M., & Nygaard, I. (2014)	Baker, J., Costa, D., & Nygaard, I. (2012)
Outcome measures	Voiding diary OAB-q SF SQoL OAB-q SF HRQL PGI-I	3-day bladder diary OAB-q SF SQoL OAB-q SF HRQL PGI-I
Statistics	Nonparametric analysis Both ITT and per protocol analysis were analyzed	Parameters of power 80%, > = 0.05 (<i>SD</i> , 1.9), <i>C</i> = 1.5 Both ITT and per protocol analysis were analyzed
Allocation assignment	Block randomization	N/A
<i>p</i> value	$p < .05$ considered significant “no trends toward statistically significant differences in the 3 different sessions of the groups about response to primary or secondary measurements”	$p = .0005$
Effect size	Not available	Not available

3.8 References

- Abrams, P., Cardozo, L., Fall, M., Griffiths, D., Rosier, P., Ulmsten, U., ... Standardisation Sub-Committee of the International Continence Society. (2003). The standardization of terminology in lower urinary tract function: Report from the standardization sub-committee of the International Continence Society. *Urology*, 61(1), 37-49.
- Alhasso, A. A., McKinlay, J., Patrick, K., & Stewart, L. (2006). Anticholinergic drugs versus non-drug active therapies for overactive bladder syndrome in adults. *Cochrane Database of Systematic Reviews*, (4), CD003193. doi:10.1002/14651858.CD003193.pub3
- Andersson, K. E. (2002). Bladder activation: Afferent mechanisms. *Urology*, 59(5 Suppl 1), 43-50.
- Baker, J., Costa, D., Guarino, J. M., & Nygaard, I. (2014). Comparison of mindfulness-based stress reduction versus yoga on urinary urge incontinence: A randomized pilot study, with 6-month and 1-year follow-up visits. *Female Pelvic Medicine and Reconstructive Surgery*, 20(3), 141-146. doi:10.1097/spv.0000000000000061
- Baker, J., Costa, D., & Nygaard, I. (2012). Mindfulness-based stress reduction for treatment of urinary urge incontinence: A pilot study. *Female Pelvic Medicine and Reconstructive Surgery*, 18(1), 46-49. doi:10.1097/SPV.0b013e31824107a6
- Coyne, K. S., Sexton, C. C., Irwin, D. E., Kopp, Z. S., Kelleher, C. J., & Milsom, I. (2008). The impact of overactive bladder, incontinence and other lower urinary tract symptoms on quality of life, work productivity, sexuality and emotional well-being in men and women: Results from the EPIC study. *BJU International*, 101(11), 1388-1395. doi:10.1111/j.1464-410X.2008.07601.x
- Devlin, G. (2010). Women and elderly: Subgroups under-represented in clinical trials. *Current Opinion in Cardiology*, 25(4), 335-339. doi:10.1097/HCO.0b013e328338bcab
- Fowler, C. J., Griffiths, D., & de Groat, W. C. (2008). The neural control of micturition. *Nature Reviews Neuroscience*, 9(6), 453-466. doi:10.1038/nrn2401
- Franco, I. (2011). The central nervous system and its role in bowel and bladder control. *Current Urology Reports*, 12(2), 153-157. doi:10.1007/s11934-010-0167-8
- Ganz, M. L., Smalarz, A. M., Krupski, T. L., Anger, J. T., Hu, J. C., Wittrup-Jensen, K. U., & Pashos, C. L. (2010). Economic costs of overactive bladder in the United States. *Urology*, 75(3), 526-532, 532 e521-518. doi:10.1016/j.urology.2009.06.096
- Griffiths, D., Tadic, S. D., Schaefer, W., & Resnick, N. M. (2007). Cerebral control of

- the bladder in normal and urge-incontinent women. *Neuroimage*, 37(1), 1-7. doi:10.1016/j.neuroimage.2007.04.061
- Grossman, P., Niemann, L., Schmidt, S., & Walach, H. (2004). Mindfulness-based stress reduction and health benefits. A meta-analysis. *Journal of Psychosomatic Research*, 57(1), 35-43. doi:10.1016/S0022-3999(03)00573-7
- Hartmann, K. E., McPheeters, M. L., Biller, D. H., Ward, R. M., McKoy, J. N., Jerome, R. N., Micucci, S. R., Meints, L., Fisher, J. A., Scott, T. A., Slaughter, J. C., Blume, J. D. (2009). Treatment of overactive bladder in women. *Evidence Report Technology Assessment (Full Report)*(187), 1-120, v. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/19947666>
- Hubeaux, K., Deffieux, X., Raibaut, P., Le Breton, F., Jousse, M., & Amarenco, G. (2011). Evidence for autonomic nervous system dysfunction in females with idiopathic overactive bladder syndrome. *Neurourology and Urodynamics*, 30(8), 1467-1472. doi:10.1002/nau.21154
- Im, H. W., Kim, M. D., Kim, J. C., & Choi, J. B. (2010). Autonomous nervous system activity in women with detrusor overactivity. *Korean Journal of Urology*, 51(3), 183-186. doi:10.4111/kju.2010.51.3.183
- MacCoon, D. G., Imel, Z. E., Rosenkranz, M. A., Sheftel, J. G., Weng, H. Y., Sullivan, J. C., ... Lutz, A. (2012). The validation of an active control intervention for mindfulness based stress reduction (MBSR). *Behaviour Research and Therapy*, 50(1), 3-12. doi:10.1016/j.brat.2011.10.011
- Mannesse, C. K., Derkx, F., De Ridder, M., & van der Cammen, T. (2000). Contribution of adverse drug reactions to hospital admission of older patients. *Age and Ageing*, 29(1), 35-39. Retrieved from <http://ageing.oxfordjournals.org/content/29/1/35.full.pdf>
- Markland, A. D., Richter, H. E., Fwu, C. W., Eggers, P., & Kusek, J. W. (2011). Prevalence and trends of urinary incontinence in adults in the United States, 2001 to 2008. *Journal of Urology*, 186(2), 589-593. doi:10.1016/j.juro.2011.03.114
- Milsom, I., Coyne, K. S., Nicholson, S., Kvasz, M., Chen, C. I., & Wein, A. J. (2014). Global prevalence and economic burden of urgency urinary incontinence: A systematic review. *European Urology*, 65(1), 79-95. doi:10.1016/j.eururo.2013.08.031
- Nitti, V. W. (2001). The prevalence of urinary incontinence. *Reviews in Urology*, 3 Suppl 1, S2-6. 21(5), 523-528. doi:10.1007/s00192-009-1069-5
- Onukwugha, E., Zuckerman, I. H., McNally, D., Coyne, K. S., Vats, V., & Mullins, C. D. (2009). The total economic burden of overactive bladder in the United States: A disease-specific approach. *American Journal of Managed Care*, 15(4 Suppl),

S90-97.

- Qaseem, A., Forciea, M. A., Starkey, M., Denberg, T. D., & Shekelle, P. (2014). Nonsurgical management of urinary incontinence in women: A clinical practice guideline from the American College of Physicians Nonsurgical Management of Urinary Incontinence in Women. *Annals of Internal Medicine*, 161(6), 429-440.
- Subak, L. L., Wing, R., West, D. S., Franklin, F., Vittinghoff, E., Creasman, J. M., ... PRIDE Investigators. (2009). Weight loss to treat urinary incontinence in overweight and obese women. *New England Journal of Medicine*, 360(5), 481-490. doi:10.1056/NEJMoa0806375
- Tenfelde, S., & Janusek, L. W. (2014). Yoga: A biobehavioral approach to reduce symptom distress in women with urge urinary incontinence. *Journal of Alternative and Complementary Medicine*, 20(10), 737-742. doi:10.1089/acm.2013.0308
- Wing, R. R., West, D. S., Grady, D., Creasman, J. M., Richter, H. E., Myers, D., ... Program to Reduce Incontinence by Diet and Exercise Group. (2010). Effect of weight loss on urinary incontinence in overweight and obese women: Results at 12 and 18 months. *Journal of Urology*, 184(3), 1005-1010. doi:10.1016/j.juro.2010.05.031

CHAPTER 4

METHODS

Symptoms of urinary leakage with urgency (known as urge urinary incontinence, or UUI) are common, disproportionately affect older women, and can be socially and psychologically devastating. Mindfulness-based stress reduction (MBSR) appears to be a favorable therapy for some women with UUI (Baker, Costa, Guarino, & Nygaard, 2014; Baker, Costa, & Nygaard, 2012). While men to a lesser extent do have UUI, the etiology of symptoms differs from that of women. For men, UUI is primarily due to bladder outlet obstruction due to an enlarged prostate, which would be unlikely to respond to MBSR. Therefore, this study is directed solely to women.

4.1 Design Overview

This research study explored the feasibility and preliminary efficacy of treating urge urinary incontinence (UUI) in older adult women with mindfulness-based stress reduction (MBSR) in comparison to the health enhancement program (HEP) through a randomized controlled pilot study. Feasibility determinants included both research feasibility (recruitment, retention, treatment fidelity) and intervention feasibility (acceptability, tolerability, treatment adherence). Clinical outcomes to evaluate preliminary intervention efficacy included severity of UUI symptoms, bother of UUI symptoms, perceived stress, and perceived level of self-efficacy of self-management of UUI symptoms. Preliminary efficacy of the intervention was also evaluated with the Patient Global Impression of Improvement (PGI-I), a process measure that rates the patient's "response of a condition to a therapy" (Ryan, n.d., p. 1; Yalcin & Bump, 2003).

This combined pilot feasibility study and randomized controlled trial (RCT) evaluated specific factors crucial to the success of a large trial to evaluate the effect of

MBSR on UUI in older adult women. Moore (2011) recommended that the pilot study design parallel the future larger study, particularly when evaluating feasibility in the pilot study. The capacity for hypothesis testing, or establishing causal inference is limited in a pilot study due to insufficient power; however, the information from efficacy testing is vital in informing future larger scale clinical trials (Leon, 2011). This study serves as a necessary step for the development of effectiveness trials of MBSR in treatment of UUI in older adult women by informing and guiding evaluation, implementation, and dissemination.

- Aim 1: To determine the research feasibility of an RCT comparing MBSR and HEP in older adult women presenting with UUI, measured by recruitment, retention, and treatment fidelity.
- Aim 2: To determine the intervention feasibility of an RCT comparing MBSR and HEP in older adult women presenting with UUI, measured by acceptability, tolerability, and treatment adherence.
- Exploratory aim: To evaluate short term preliminary efficacy of MBSR for treatment of UUI in older adult women, in comparison to HEP, measured by symptom severity, symptom bother, perceived stress, perceived self-efficacy, and the trajectory of change.

4.2 Intervention Description

The overarching goal of this research is to evaluate potential treatment options for older women with symptoms of UUI, with a specific focus on MBSR, a promising therapeutic approach in preliminary studies and one increasingly used to treat symptoms

associated with brain-visceral interactions (Grossman, Niemann, Schmidt, Walach, 2004; Kabat-Zinn, 2005). Feasibility and preliminary efficacy were tested in two randomized study arms: an MBSR intervention condition and an HEP intervention comparison condition. According to the literature, pilot studies are better poised to address their goals when study design incorporates comparison conditions (Leon, 2011). The comparison condition decision was made in concordance with the state of the science of the current intervention, as delineated in Section 4.12.1 (Nezu & Nezu, 2008). The reasoning is provided below in the *Rationale for Selection of the Comparison Condition* section.

The interventionists in these two study conditions were certified and credentialed. Because of the sensitive nature of the condition, UUI, I elected to hire female interventionists for both treatment arms.

4.2.1 Mindfulness-Based Stress Reduction (MBSR)

Mindfulness-Based Stress Reduction is an 8-week psychosocial intervention delivered in a group setting. Participants attend nine total sessions, meeting for 2 hours each week for 8 weeks, with a retreat between weeks 6 and 7. Class instruction is augmented by daily home practice, consisting of listening to audio meditation recordings, practicing mindfulness skills, and completing weekly readings and self-reflection assignments. Homework (practice) is provided to each participant. This is the standard, protocolled MBSR, which I employed. Hence, the outcomes of this study can be compared with other biobehavioral studies of MBSR. The intervention was led by a certified MBSR instructor.

4.2.2 Health Enhancement Program (HEP) Comparison Condition

The Health Enhancement Program is also an 8-week psychosocial intervention delivered in a group setting (MacCoon, 2012). Identical to MBSR in its format, participants meet in nine sessions, 2 hours a week for 8 weeks, with a retreat between weeks 6 and 7. Class instruction is supplemented with weekly homework, much like the MBSR practice. Please see Section 4.12.2 for a comparison of the MBSR and HEP curricula. The Health Enhancement Program in itself is a detailed, clearly spelled-out intervention with each session's content, homework, and interventionist's interactions with the participants thoroughly delineated. The HEP protocol is a substantive active comparison condition, which delivers "skillful provision of common therapeutic elements" (MacCoon et al., 2012, p. 4) so as to not bias tests of intervention effects (Mohr et al., 2009). The HEP was taught by a certified health education specialist (CHES).

4.2.3 Rationale for Selection of the Comparison Condition

The HEP condition is responsive to the National Institutes of Health's call to researchers to provide a comparison condition for MBSR studies that is of equivalent commitment and experience (Ospina et al., 2008). HEP has been previously validated for use as a comparison condition alongside an MBSR intervention and meets the following criteria: (1) class activities match MBSR activities as closely as possible; (2) these activities represent valid, active, therapeutic ingredients in their own right; and (3) these ingredients do not include mindfulness (MacCoon et al., 2012). The HEP is designed to match MBSR in 1) positive expectations of success by teacher and participant, 2) an

ongoing relationship between teacher and participant, 3) a conceptual framework supporting participant's actions, and 4) specific actions and instructions for participant to follow (Kok et al., 2013).

Using HEP as a comparison condition strengthened this RCT, as it is an active control condition for MBSR while remaining inert to mindfulness. It is credible to both participants and providers and offers a plausible alternative for success through therapeutic rationale.

4.3 Participants

Twenty-five postmenopausal females with UUI were recruited as participants into this study. My enrollment target range was 12-30 participants. I sought to enroll enough participants to obtain sufficient enrollment at completion, given typical attrition rates of 15-20% (as high as 30% in one MBSR study) in the older adult population (Creswell et al., 2012; White et al., 2010).

Interested women completed a brief screening over the phone. Screening confirmed the following eligibility and exclusion criteria:

4.3.1 Eligibility Criteria

The study enrolled older adult women with UUI. They could not be currently treating their UUI with medication, even hormone therapy, as this would have confounded results. Women who had attempted more extreme treatments and were still experiencing UUI were not considered as potential participants, as it would have been unlikely that MBSR would treat UUI that was refractory to that degree. Participants had

to be English speaking, as the interventions and homework were delivered in English. In summary, participants needed to:

- Be postmenopausal, with an emphasis on older adult women, aged 65+.
- Have urge predominant urinary incontinence, defined as score of > 3 (moderate to severe urinary incontinence) on the Incontinence Severity Index (see Section 4.12.3) and predominant UUI as determined by question 3 on the 3 Incontinence Questions (see Section 4.12.4; Brown et al., 2006). The 3 Incontinence Questions (3IQ) has been shown to be a quick and accurate way of diagnosing stress, urge, or mixed incontinence in most cases (Brown et al., 2006; Holroyd-Leduc, Tannenbaum, Thorpe, & Straus, 2008; Rohr, Christensen, Ulstrup, & Kragstrup, 2004).
- Have experienced urge urinary incontinence symptoms for at least 3 months.
- Be committed to attend eight weekly sessions and one half day retreat between weeks 6 and 7.
- Have no pharmacologic therapy for UUI within 3 weeks of enrollment and no plan to initiate such medications during the 8-week active treatment (eligible women who tapered off their medication to none by 3 weeks before the intervention began were included).
- Plan to remain on hormone therapy or vaginal estrogen for the duration of the study if they were currently on it at enrollment; if not on it, have no plan to initiate.
- Have had no previous intradetrusor Botox injection for UUI and no plan to receive it during the intervention.

- Have had no previous neurostimulation for UUI and no plan to receive it during the intervention.
- Be English speaking.

4.3.2 Exclusion Criteria

The following exclusions were applied, as they could seriously limit participation or confound participant response to the intervention. Potential participants were asked to self-report on:

- Predominantly stress, mixed, or other type of incontinence as determined by question 3 on the 3 Incontinence Questions (see Section 4.12.4).
- Currently taking medications for Alzheimer’s disease or other dementias; these medications could interfere with their participation.
- Known neurologic disease acknowledged to impact bladder function, including Parkinson’s disease, spinal cord injury, or stroke affecting urinary control; these diseases provide cause for UUI and as such the participant would be unlikely to benefit from the intervention.
- Current symptomatic urinary tract infection that did not resolve prior to the start of intervention.
- Current bladder infection that did not resolve prior to the start of intervention.
- Use of an assistive device for ambulation (such as a cane, walker, or wheelchair) *and* feels that difficulties with bladder management are related to the slowed time in visiting the restroom (“Was UUI a problem before you began using the assistive device?”).

- Functionally incontinent, that is, having a mental or physical condition that prevents a person from visiting the restroom in time.
- Ever diagnosed with interstitial cystitis.
- Self-report of vaginal bulge protruding outside of the vagina.
- Past participation in a formal program of MBSR.
- Substantial, uncorrected hearing loss that would affect participation in a group setting (self-reported).
- Substantial, uncorrected vision loss that would affect seeing projected slides or other class instruction (self-reported).
- Limitations that preclude completing study questionnaires or surveys, such as difficulties with reading and writing.

For this study, I did not exclude women based on medication use other than medications used to treat UUI. I assessed participants' use of antidepressant or anxiolytic medications, medications for sleep, pain management, and beta-blockers and whether or not their regimen was stable for 8 weeks before enrollment (Moynihan et al., 2013).

Potential participants who declined or were excluded were referred to their urogynecological caregiver if they inquired regarding treatment (Corsini-Munt, Bergeron, Rosen, Mayrand, & Delisle, 2014).

In addition, I excluded women with a moderate to severe cognitive impairment, defined as a score of < 25 on the Montreal Cognitive Assessment (MoCA; Nasreddine, 2010; Nasreddine et al., 2005), see Section 4.12.5, as the intensity and focus of the interventions necessitated that participants be cognitively engaged. Because this cannot be assessed over the phone during screening, it was assessed at the enrollment interview

as described in the *Enhanced Enrollment* section under *Procedure* below.

4.3.3 Compensation

I provided a total of \$100 in gift card compensation to study participants. Participants who did not complete the study received a prorated amount of compensation. Compensation was staggered across the study for all participants, with \$40 given after the retreat session between weeks 6 and 7 and the remaining \$60 given at completion of measures at the last session. Public transportation passes and parking validations were provided.

4.4 Recruitment

Recruitment of older adults carries particular cautions; according to McHenry and colleagues (2015), it can be improved by cultivating relationships with community-based organizations, face-to-face contact with potential study participants, and providing service as an access point to eligible participants. According to Leon (2011), pilot sample size should be based on “the pragmatics of recruitment and the necessities for examining feasibility.”

To minimize the risk of embarrassment from participating in the project, the study was advertised as a “Bladder health” and “Bladder management” study. Once the program began, it was scheduled and posted simply as “Mindfulness study” and “Health enhancement study” and did not refer to urinary incontinence.

Participants were recruited from the University of Utah Health Sciences network, including the Pelvic Care & Incontinence Center, the Geriatrics Clinic, the Sleep-Wake

Center, and other germane health care provider units utilized by older adult women at the University of Utah Health Sciences Center (UUHSC) as well as other University of Utah Health Care clinics throughout the community. Fliers were posted in the School of Medicine, the College of Nursing, and the Health Sciences Education Building bulletin boards and women's restrooms as well. Recruitment also included the Osher Lifelong Learning Institute on campus. The Osher Lifelong Learning Institute offers noncredit learning opportunities and engagement for adults 50 and older. They provided email blasts and I presented a "lunch and lecture" on urinary incontinence. Additionally, I gave a presentation at an Integrative Health and Resiliency conference on campus, which is attended by members of the community.

Further, two databases within the University of Utah Health Sciences Center were used to recruit participants. The Center on Aging has a participant registry and the university has a Research Match division. Both were matched for age and gender and recruitment fliers were sent via email. Potential participants responded via return email, text, or phone call.

Recruitment also included Salt Lake County senior centers, which necessitated an additional Institutional Review Board application, through the Utah State Department of Health and Human Services. Salt Lake County Aging and Adult Services has 19 senior centers and nine affordable senior living apartments under its purview. Salt Lake County Aging and Adult Services approved the IRB proposal to recruit at Salt Lake County senior centers. I recruited at these centers by posting fliers in the women's restrooms and on their bulletin boards, and by giving short presentations regarding urinary incontinence to any interested center participants, and serving as a vendor at several senior center

health fairs, often in collaboration with the university's Director of Research Participant Advocacy who represented Research Match.

Further recruitment included fliers posted on bulletin boards in the community, provider referrals, and word of mouth recruitment. After gaining permission from the various managers, I posted fliers in grocery stores, pharmacies, coffee shops, recreational centers, libraries, and other community spots. The Utah Commission on Aging was helpful in providing networking connections to places of interest in the community. When allowed, I posted fliers inside stalls of the women's restrooms. The exposure in the restrooms allowed for a private view of the study advertisement and the chance for the potential participant to remove the tear off portion without anyone else seeing them do so. I also presented at a booth at a regional KUTV Health Fair held in a local convention center. Success rates of various recruitment strategies were tracked.

4.5 Procedure

4.5.1 Screening

Participant screening occurred on the phone with interested respondents. When potential participants called, I explained the basic framework of the study, the general time commitment, the transportation options, and the remuneration. For the purposes of transparency and reproducibility, a screening script was followed (see Section 4.12.6). When the participant expressed interest, the eligibility and exclusion criteria were reviewed, one at a time. When a potential participant qualified for the study, she was invited to come in for an enrollment interview.

This enrollment interview took place in the same location as the intervention

classes to facilitate participant comfort in the logistics of location and parking. I sent a map and instructions for navigation and parking via email or postal service mail, and I met the participant at the parking garage. I then escorted them to the building where the enrollment interview, and eventually the course itself, took place. This enhanced enrollment procedure allowed participants an advance orientation to the study site, increasing the participant's ease and facilitating retention (McHenry, 2015).

4.5.2 Informed Consent

At the interview, potential participants who met the eligibility criteria were provided with an informed consent document. The consent document, along with all study information, was written with 14 font size or greater, in serif font, in black type on matte, white paper, and double spaced, to accommodate this population (Kicklighter, 1991; National Institute on Aging, 2008). The language used in both oral and written communication throughout the entire study process was as nontechnical as possible (U.S. Department of Health and Human Services, 1996). After giving the participant ample time to read the document and ask questions, I reviewed the consent document with participants paragraph by paragraph. Thus, participants were informed of the confidentiality guidelines of participation and given a signed copy of the consent document to take home.

4.5.3 Enhanced Enrollment

Upon completion of the informed consent document, I administered the MoCA and, as appropriate, proceeded with administration of the baseline measures. Only one

interviewee failed the MoCA. In this case, it was explained that the study had a cutoff for cognitive function, and the interviewee scored below it. The participant was already aware of their cognitive impairment, having been previously diagnosed with dyslexia. I informed enrolled participants of their assigned intervention while preserving the blinded-to-condition nature of the study design.

Each potential participant who came for the enrollment interview, with the exception of the potential participant with dyslexia, signed the consent document and enrolled in the study. In addition to a signed copy of the consent document, participants were also given a study summary highlighting the key features and my contact information in a clear, bulleted one-page document. Because this was an intervention delivered to a group of participants, a set of guidelines to encourage respect of confidentiality was also shared with each enrolled participant (see Section 4.12.7).

4.5.4 Randomization

As outlined in the Consolidated Standards of Reporting Trials (CONSORT) (Chan et al., 2013; Schulz, Altman, Moher, & Group, 2010), participants were assigned to their respective intervention condition through a process based on chance, which is random and cannot be predicted, to avoid selection bias or potentially biased outcomes. Participants were randomized into the MBSR or HEP condition according to the order of enrollment, and randomization was generated through the block method. The block method was utilized to ensure that enrollment was generated with a 1:1 ratio. Using blocking can increase predictability, so CONSORT recommends blinding the interventions and/or varying the block sizes to retain unpredictability (Chan et al., 2013;

Schulz et al., 2010). I applied these measures of allocation concealment. I varied the block sizes and placed the randomized condition selection into an envelope, marked with an interview number. I did not refer to the randomized result prior to the interview. Participants were blinded to the study condition. This adherence to CONSORT guidelines potentially diminishes dropout rates in the comparison condition (Chan et al., 2013; Schulz et al., 2010). Prior studies regarding methodology have provided support for such safeguards (Pildal et al., 2007; Wood et al., 2008). All study protocols, recruitment procedures, measures, and instruments were reviewed and approved by the University of Utah Institutional Review Board and the Department of Human Services Review Board prior to recruitment (UU IRB #00095461; DHS IRB #0589).

4.5.5 Data Management

Data management followed regulations for protection of human participants as well as confidentiality. The main risks for this study were breach of confidentiality and elevated distress. This was acknowledged in the informed consent document. Participants were informed of expectations of privacy and confidentiality. Good clinical practices were strictly adhered to in the study, from planning stages through completion (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996; World Health, 2005). Good clinical practices encompassed research staff training, informed consent procedures, Institutional Review Board (IRB) reporting, and monitoring/oversight procedures of both interventionists and participants (Leon, Davis, & Kraemer, 2011). These four items were documented and reviewed. Interventionists and research staff were and are CITI certified. Consent

procedure followed IRB protocol. IRB reporting was done through the University of Utah IRB and the Department of Human Services IRB. I oversaw participant monitoring during the recruitment, consent, randomization, and evaluation phases and interventionists and participants during the intervention phase. I tracked study progress including screening, demographic and clinical data, consenting, intervention, and evaluation. I was also responsible for data management, including data entry, accuracy, and integrity. All attempts to safeguard confidentiality were made using technological and physical precautions. Every effort was and continues to be taken to preserve the participants' dignity, respect, and autonomy.

Participants were assigned a study identification number to maintain a confidential environment. Data are electronically managed in Research Electronic Data Capture (REDCapTM) hosted at the University of Utah. REDCapTM is a secure, web-based application intended to support data capture for research studies. REDCapTM provides 1) an intuitive interface for validated data entry, 2) audit trails for tracking data manipulation and export procedures, 3) automated export procedures for downloads to common statistical packages, and 4) procedures for importing data from external sources.

Data were exported to IBM SPSS version 24.0 (IMB Corp, 2016) for data analysis. All research records are kept private per the IRB policy and procedures at the University of Utah. Records are kept in locked filing cabinets and entered into encrypted computers protected with passwords. A separate file linking study identification numbers with contact information is maintained. All files are kept in secure databases and secure locked filing cabinets behind locked doors at the University of Utah.

Both the CONSORT (Chan et al., 2013; Schulz et al., 2010) and Standard

Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (Chan et al., 2013) were followed.

4.6 Setting

Both intervention groups were held in comfortable, small classrooms at the University of Utah College of Nursing in the late afternoon to avoid conflicts with academic classes. Screens were placed outside the classroom door to provide privacy to participants.

4.7 Measures

4.7.1 Demographics

Participants' age, race, ethnicity, BMI, caffeine intake, and medication use were recorded at the enrollment interview after participant consent was obtained. The demographics questionnaire is included in Section 4.12.8. Demographic collection at baseline also included date of birth, marital status, race/ethnicity, education, brief gynecologic and medical history, brief UUI history, previous treatment for UUI, weight, height, medication use, life satisfaction, and life stress. Caffeine use and medication were recorded again at completion of study, to determine whether or not use remained constant throughout the study.

4.7.2 Feasibility Measures

The feasibility measures are divided into research feasibility measures, having to do with the research process, and intervention feasibility measures, having to do with the

participant process and outcome. See Section 4.12.9 for scheduled administration of measures.

4.7.2.1 Research Feasibility Measures

The rationale for my selected research feasibility measures, which are defined individually below, is drawn from the recommendations of Lancaster, Dodd, and Williamson; Leon, Davis, and Kraemer; Thabane et al.; Nezu and Nezu; and others (Lancaster, Dodd, & Williamson, 2004; Leon, Davis, & Kraemer, 2011; Nezu & Nezu, 2008; Thabane et al., 2010; Tickle-Degnen, 2013). These researchers recommended incorporating the following measures in pilot studies to evaluate the capacity of the research team to properly and successfully conduct a larger study.

Consent rate is an important determinant for feasibility studies, as these studies are typically conducted in preparation for a larger scale trial (Lancaster et al., 2004).

Treatment fidelity measures how closely an intervention is delivered in comparison to how it was drafted and designed (Hildebrand et al., 2012). Hildebrand and colleagues (2012) explain that the absence of demonstrated treatment fidelity threatens internal and external validity of observed outcomes. Treatment fidelity was evaluated in both interventions through five recognized standard of science elements: study design, provider training, treatment delivery, treatment receipt, and enactment of treatment skills (Bellg et al., 2004).

To ensure treatment fidelity in study design, the treatment dose was applied evenly to all participants, within and across conditions. To minimize contamination across treatment and comparison conditions, the two interventions' meetings were

conducted on separate days, so interventionists and participants from each condition did not ever interact with the other condition. Participants were blinded to condition.

Interventionists and participants from both conditions never met or interacted with one another, avoiding confounding the study.

To ensure treatment fidelity in provider training, I confirmed that interventionists met a priori performance criteria and operated from their respective standardized manuals. I also ensured that interventionists delivered their separate interventions in similar ways, with standardized materials, length of class, and assessments. I documented their respective certification and credentials.

Treatment delivery refers to the adherence of the interventionists to the intervention protocols. Since the weekly interventions were not recorded, and since interventionists may overestimate the content addressed, it is valuable to measure treatment delivery from both the interventionist and participant perspective. To ensure treatment fidelity in treatment delivery, I met with each interventionist after each session and asked them to verify what they delivered and compared it with what was planned. Additionally, I administered brief treatment delivery checklists to participants at the completion of the intervention, asking participants to mark the items that were taught throughout the course of the intervention. Since there was no video or audio recording of the weekly interventions, treatment delivery was measured both from the interventionists' and the participants' perceptions to triangulate the data. I also confirmed the availability of substitute interventionists for each condition should the primary interventionist be unable to lead a session. This occurred once for each interventionist and course. A certified substitute was obtained and participants expressed comfort with and confidence

in the substitute.

To ensure treatment fidelity in treatment receipt, I confirmed with the interventionists that participants understood the information provided in the intervention. This was evaluated by having the interventionists ask questions and discuss materials with participants and collect self-monitoring/self-reporting data. Participants proved eager to have these discussions weekly in class as well as outside of class with the instructor who made themselves available.

To ensure treatment fidelity in enactment of treatment skills, I verified that interventionists have processes in place that allow them to “monitor and improve the ability of [participants] to perform treatment-related behavioral skills” (Bellg et al., 2004, p. 448). These processes included monitoring and giving feedback on practice sessions, as well as collecting homework data and logs.

4.7.2.1.1 Recruitment

Recruitment was measured as number of people enrolled (Thabane et al., 2010). I determined referral source (Wesson et al., 2013). I measured the ratio of contacted to enrolled and recorded reasons for exclusion (by researcher) or declining (by respondent).

4.7.2.1.2 Retention

Retention was measured as percent of enrolled participants completing the study and accounted for reasons for attrition (Leon et al., 2006). If a participant did not attend a session, a courteous follow-up telephone call was placed, exploring what the attendance challenge may have been. These data were recorded in field notes and the information

was handled as protected data.

4.7.2.1.3 Treatment Fidelity

Treatment fidelity was measured by documenting how study design, provider training, treatment receipt, and enactment of treatment skills were addressed throughout the study. Treatment delivery was measured by consulting with the interventionists after each session, noting what they were scheduled to do and asking them to relate what they did. We met directly after each week's intervention to confirm that treatment integrity objectives were met. A 75% or higher achievement on these objectives was considered the standard confirming objectives being met (Nezu & Nezu, 2008). Treatment delivery was also measured by a checklist given to participants at study completion, to mark those concepts covered in the weekly interventions. A 75% or higher achievement on these participants' reports is typically the standard to confirm the interventionists' concordance with their respective intervention protocols (Nezu & Nezu, 2008).

4.7.2.2 Intervention Feasibility Measures

The rationale for my selected intervention feasibility measures, listed individually below, is also drawn from the scientific literature regarding feasibility studies (Arain, Campbell, Cooper, & Lancaster, 2010; Bowen et al., 2009; Lancaster et al., 2004; Morin, 2013; Sturdy et al., 2003). Lancaster (2004) and colleagues recommend determining acceptability in a pilot study.

4.7.2.2.1 Acceptability

Acceptability was measured as a positive versus negative response to the question, “How did it go today?” Following each session, two randomly selected participants in each intervention were approached by me and assessed on this acceptability question. The aggregate data were analyzed.

4.7.2.2.2 Tolerability

Tolerability was measured as number of dropouts due to stated distress from or dislike of either intervention experience, as opposed to someone needing to withdraw due to a family emergency or illness. (Moore, 2011; Sturdy, 2013). Participants who withdrew were asked to respond to a single question, “Help me understand what made this challenging?”

4.7.2.2.3 Treatment Adherence

Treatment adherence was measured by attendance and homework completion at each session, as recorded by the interventionists. Attendance was tracked as excused versus unexcused. Participants submitted each week’s homework to evidence homework completion and this was tallied and recorded (measured as turned in/not turned in).

4.7.2.3 Preliminary Efficacy Measures

The four measures of preliminary efficacy, the Incontinence Severity Index (ISI), the Overactive Bladder Questionnaire Short Form (OAB-q SF), the Perceived Stress Scale (PSS), and the Geriatric Self-Efficacy Index for Urinary Incontinence (GSE-UI),

were administered at baseline and again at study completion. Immediately following the final intervention session, participants received study instruments to be filled out and collected. Participants received their final gift cards at this time. These measures needed to be $\geq 75\%$ completed to be included in data analysis. They were collected from all enrollees, even those who dropped out of the classes, with the exception of one who moved out of state under duress and left no contact information.

4.7.2.3.1 Incontinence Severity Index (ISI) 2-Item Scale

The Incontinence Severity Index (Sandvik, Espuna, & Hunskaar, 2006; Sandvik, Seim, Vanvik, & Hunskaar, 2000) is a short, simple, and sensitive measure of urinary incontinence in women. Sandvik and colleagues (2006) reported that the ISI demonstrated “good criterion validity and good construct validity” (p. 520). Pereira and colleagues reported satisfactory survey validity (Pereira, Santos, Correia, & Driusso, 2011). Murphy and colleagues reported strong convergent validity of the ISI as well (Black, Griffiths, & Pope, 1996; Murphy et al., 2006). While no English research article reports a Cronbach’s alpha (α) reliability value for the ISI, the earlier cited Portuguese study by Pereira and colleagues reported that Cronbach’s α coefficient = 0.93, evidencing “excellent reliability and consistency of the [ISI] instrument” (Pereira et al., 2011). Pereira and colleagues (2011) also reported intraclass correlation coefficient and standard errors of measurement at 0.96 and 0.43. The Pearson correlation between the ISI and pad test revealed a strong positive one ($r = 0.72, p < .0001$; Pereira et al., 2011).

Categories of ISI are divided into None (0), Slight (1-2), Moderate (3-6), Severe (8-9), and Very Severe (12). The ISI was administered at baseline and at study

completion. See Section 4.12.3. Adequate completion of the ISI: completion of two items and only one possible response checked for each question.

4.7.2.3.2 Overactive Bladder Questionnaire Short Form (OAB-q SF),

19-Item Scale

The Overactive Bladder Questionnaire Short Form (K. S. Coyne, Thompson, Lai, & Sexton, 2015) measures symptom bother on a Likert-type scale from 1 (not at all) to 6 (a very great deal). The OAB-q is a “reliable and valid instrument” (K. Coyne et al., 2002, p. 563), able to differentiate between participants with and without overactive bladder incontinence (K. S. Coyne et al., 2015). K. Coyne and colleagues (2002) reported Cronbach α values ranging from 0.86 to 0.94. The OAB-q shows that overactive bladder symptoms cause substantial symptom bother and “have a negative impact on HRQL” (K. Coyne et al., 2002). While the OAB is validated as a single 19-point scale (PRO4Pfizer representative Sheryl, personal communication, August 26, 2016) to measure bother, it can also be viewed within its two parts. Part 1 (Q1-6) addresses severity and Part 2 (Q1-13), often called HRQL, addresses bother. K.S. Coyne (2015) and colleagues demonstrated that the OAB-q SF has “good convergent validity, discriminant validity, internal reliability, and reproducibility” (K.S. Coyne et al., 2015, p. 255). The OAB-q SF was administered at baseline and at study completion. See Section 4.12.10.

Adequate completion of the OAB-q SF: completion of at least 15 items, with only 1 of 6 possible response items checked for those questions. This is a 79% completion rate.

4.7.2.3.3 Perceived Stress Scale (PSS-10), 10-Item Scale

The Perceived Stress Scale (Cohen, Kamarck, & Mermelstein, 1983; Cohen, Kessler, Underwood Gordon, 1995; Cohen & Williamson, 1988) measures stress in the last month on a Likert-type scale from 0 (never) to 4 (very often). Scores range from 0 to 40; higher scores relate to higher levels of perceived stress. Notably for this study, it has been shown to correlate with physical symptomatology (Cohen & Williamson, 1988; Gallegos, Lytle, Moynihan, & Talbot, 2015). Cohen and colleagues (1983) state that the PSS demonstrates “substantial reliability and validity” (Cohen et al., p. 394) and presented coefficient α reliability at 0.84, 0.85, 0.86 in three separate samples; notably for application in the current study, the authors found “age was unrelated to PSS” (Cohen et al., 1983, p. 390) and there were no differences between males and females. The PSS has four questions that are reverse scored, and this was employed during data analysis. The PSS-10 was administered at baseline and at study completion. See Section 4.12.11.

Adequate completion of the PSS-10: completion of at least 8 of 10 items, with only one of 4 possible response items checked for at least 8 questions. This is an 80% completion rate.

4.7.2.3.4 Geriatric Self-Efficacy Index for Urinary Incontinence (GSE-UI), 13-Item Scale, Adapted

The GSE-UI measures self-efficacy with regard to urinary incontinence in older adults. The index is significantly correlated with “symptom severity and impact on everyday life” (Tannenbaum, 2008, p. 544). As I measured severity and bother as two distinct outcome measures, this correlation is a noteworthy one. The GSE-UI has a

sensitivity of 0.75 and a specificity of 0.78 (Tannenbaum et al., 2008; Tannenbaum et al., 2009). Tannenbaum reported Cronbach's $\alpha = 0.90$ (Tannenbaum et al., 2009). To measure participant self-efficacy regarding the skillset participants gained in their respective interventions, I included one self-efficacy question using Bandura's guidelines (Bandura, 2006): "How confident are you that you can implement the elements of what you learned to manage your urine control?" Thus, the GSE-UI scale as adapted for this study has 13 questions. Scores range from 0 to 130, and responses are recorded on a Likert-type scale from 0 (not confident) to 10 (very confident). The adapted GSE-UI was administered at baseline and at study completion (see Section 4.12.12). Adequate completion of the adapted GSE-UI consisted of completion of at least 10 of 13 items, with only 1 of 10 possible response items circled for each of those 10 questions. This is a 77% completion rate.

4.7.2.4 Process Measure

4.7.2.4.1 Patient Global Impression of Improvement (PGI-I), 1-Item Scale

As this feasibility study is to inform the potential for a future, larger scale trial, it is important to note at what stage of the treatment any changes, whether positive or negative, occur. A Patient Global Impression of Improvement measure was used in both conditions throughout the intervention phase to assess the process of change. Each participant filled out a Patient Global Impression of Improvement after each session, measuring their own responsiveness to the intervention. While this added a slight amount of participant burden, it allowed me to see if and when effects were seen. The PGI-I has "established construct validity" (Yalcin & Bump, 2003, p. 98) for treatment response in

reference to incontinence. Srikrishna, Robinson, and Cardozo (2010) noted that the PGI-I has been validated specifically in incontinence and that it shows “excellent test-retest reliability” (Yalcin, 2003, p. 523). The PGI-I was administered after each study session, for a total of nine times (8 weeks plus retreat between weeks 6 and 7). See Section 4.12.13. Adequate completion: one item answered with one choice selected.

4.8 Analytic Plan

There are five components to my analytic plan: analysis of demographics, research feasibility measures, intervention feasibility measures, outcome measures, and process measures. After completion of all data collection, data were entered into REDCapTM. Since data entry was completed by one person, it was checked by a second member of the research staff, Daniela McCroby. Discrepancies were noted by the second team member and I checked the original participant paper form and entered the corrected data into REDCapTM. Data were exported to IBM SPSS version 24.0 for all analyses (IBM Corp., 2016).

I conducted preanalysis of data, running frequency statistics for missing data and outliers. If not attended to, missing data and outliers could affect my assumptions for normal distribution. Categorical variables were checked by noting minimum and maximum values, noting valid and missing cases, and finding out where any errors occur. Continuous variables were also checked by noting minimum and maximum variables, noting the mean score, and then considering if these values seem sensible or if something appears out of range. The SPSS function, Summarize Cases, was also helpful to the data cleaning process. As explained by Van den Broeck and colleagues (2005), after

identification of errors, three options are available to the researcher: correcting, deleting, or leaving the error unchanged. Data cleaning is a study-specific process to some degree, but I followed the general guidelines as recommended by Van den Broeck et al. (2005). When missing data needed to be imputed within the Patient Global Impression of Improvement, I assumed that the previous measure stands.

I conducted preanalysis of my demographic variables to evaluate if the sample within each treatment arm were similar. Gender was not compared between conditions, as I recruited women only. I utilized chi square tests on the categorical demographic variables (race and ethnicity) and independent t tests on the continuous variables: age, BMI, Incontinence Severity Index score, Montreal Cognitive Assessment (MoCA) score, medication use, and caffeine use, to evaluate whether the MBSR and HEP conditions were comparable. When my distributions for variables did not achieve normality, I was unable to use independent t tests and instead used Mann-Whitney U tests, the nonparametric version of independent t tests.

Analysis of research feasibility measures, intervention feasibility measures, outcome measures, and the process measure is addressed in response to each study aim described below. Section 4.12.9 provides an overview of these measures.

4.8.1 Aim 1

Aim 1 was to determine the **research feasibility** of MBSR and HEP implementation in older adult women presenting with UUI. Research feasibility determinants include recruitment, retention, and treatment fidelity.

Data analysis for the recruitment and retention portions of this aim were

performed through descriptive statistics, displayed in a CONSORT flowchart illustrating the number of participants who were screened, met eligibility/exclusion criteria, enrolled, consented, participated, and completed the study. Data addressing reasons why potential participants were ineligible, why participants were not consented (exclusion and declining), and reasons for participant attrition were described in this flowchart. See Figure 2, Section 4.12.14.

To complete my understanding of research feasibility, I inquired of potential participants how they became aware of the study and noted these in my REDCap data.

Treatment fidelity consists of study design, provider training, treatment delivery, treatment receipt, and enactment of treatment skills. Study design, provider training, treatment receipt, and enactment of treatment skills were documented to evidence accomplishment as described earlier. Treatment delivery was measured by two data sources: 1) through conversations after each intervention session with respective interventionists verifying that they addressed the content they were scheduled to address, and 2) a checklist administered to participants at study completion, to determine if content was delivered per protocol. Treatment delivery is considered adequate if the interventionists' observance level equals 75% of scheduled content to be delivered, as evidenced through two data measures: 1) interventionists' verification of the individual session objectives in meetings with me following each session, and 2) participants' verification of treatment objectives on the checklist given them at completion of study.

4.8.2 Aim 2

To determine the **intervention feasibility** of MBSR implementation in older adult women presenting with UUI, in comparison to HEP implementation. Intervention feasibility determinants include acceptability, tolerability, and treatment adherence.

Data analysis was completed to evaluate the intervention feasibility determinants. *Acceptability* was recorded as participant feedback documented after each session. Two participants were randomly selected after each class and asked the question, “How did it go today?” Participant answers were coded as positive or negative expression and described as a percentage. Qualitative analysis of these data is beyond the scope of this dissertation; as such, those data will be described in written form in the respective results and discussion sections of subsequent manuscripts reporting on the study.

Tolerability is directly related to attrition and was measured as drop-out count and reported as a percentage. I inquired of those who left the study early why the intervention was challenging. Brief qualitative data were available in this regard, and as the sample size is quite small for those who left the study, I reported this information qualitatively.

Treatment adherence was measured in two ways. First, treatment adherence was measured as attendance and reported as a percentage. Homework completion was also measured and reported in percentages.

These three intervention feasibility outcomes are compared against available standard intervention feasibility measures of success (Bellg, 2004; White, 2010). However, it is critical to note that this is a pilot study—with an as yet unevaluated population—so part of my evaluation was to discern barriers to and facilitators of intervention feasibility.

4.8.3 Exploratory Aim

To evaluate short-term **preliminary efficacy** of MBSR for treatment of UUI in older adult women, in comparison to HEP implementation, including symptom severity, symptom bother, perceived stress, perceived self-efficacy, and rate and trajectory of change.

Analysis of preliminary efficacy as stated in the exploratory aim was addressed in response to the set of research questions (RQ 1-4) examining the *outcome* measures (Incontinence Severity Index [ISI], the Overactive Bladder Questionnaire Short Form [OAB-q SF], the Perceived Stress Scale [PSS], the adapted Geriatric Self-Efficacy Index for Urinary Incontinence [GSE-UI]) and the research question (RQ 5) examining the *process* measure (Patient Global Impression of Improvement [PGI-I]).

- **RQ 1:** Does MBSR reduce UUI severity in older adult women as compared to HEP?

Severity was analyzed by the ISI and informally through the OABq-SF Part 1 scores.

- **RQ 2:** Does MBSR reduce UUI bother in older adult women as compared to HEP?

Bother was analyzed by the overall and Part 2 (HRQL) scores of the OAB-q SF.

- **RQ 3:** Does MBSR reduce older adult women's perceived stress in older adult women as compared to HEP?

Perceived stress was analyzed by the PSS scores.

- **RQ 4:** Does MBSR increase older adult women's self-efficacy surrounding self-management of UUI symptoms as compared to HEP?

Perceived self-efficacy was analyzed by the adapted GSE-UI.

Each research question above was analyzed using independent samples t tests or Mann Whitney U tests (the nonparametric alternative to independent samples t tests. I analyzed the impact of the independent variable treatment condition on each dependent variable with several assumptions as put forth by Green and Salkind (2008) as well as Munro (2005).

- 1) The distribution of the dependent variable is normal. I checked this by running frequency statistics and visually evaluating the results in a histogram.
According to Green and Salkind (2008) the independent t test may “yield reasonably accurate p values even when the normality assumption is violated” (p. 176). They state that a sample size of 15 may allow this accurate yield.
- 2) The independent variable (MBSR or HEP) is categorical (nominal in this case), and the dependent variable is continuous (ISI, OAB-q SF, PSS, and GSE-UI).
- 3) The groups are mutually exclusive, meaning each participant can only contribute a score to one condition and not the other.
- 4) The variance of the individual outcome variable of the two groups is similar. I discover this in my demographics frequencies described above. This is the “requirement of homogeneity of variance” (Munro, 2005, p. 140).

According to Green and Salkind (2008) and Pallant (2013), the assumptions of the Mann-Whitney U test are less stringent than the parametric technique but include the following:

- 1) The continuous distributions for the test variable are the same (except their

medians) for the two populations.

- 2) The cases represent random samples from the two populations.
- 3) The scores on the test variable are independent of each other.
- 4) The z -approximation test requires a sample size of more than 30. It is worthy to note that the z -approximation test does not have to be used—SPSS will print an exact test if the number of cases is less than or equal to 30. This is the situation this study fits into, as total participants numbered 25.

If the assumptions for the independent t tests hold, I determine if there are significant differences between the outcome measures. I set the value of $p < .05$ as the standard for significant differences.

When I used the Mann-Whitney U test to interpret the outcome, I indicated the direction of the difference.

While the Mann Whitney U tests showed between condition differences, the within condition differences were addressed by the use of paired t tests. When paired t tests could not be used, the Wilcoxon signed-rank test was used to compare the within condition differences, that is, change from baseline to completion within the same condition (Pett, 2015).

- **RQ 5:** What is the rate and trajectory of change, as reported by participants in each condition?

To analyze the exploratory aim *process* measure, The Patient Global Impression of Improvement, linear mixed effects modeling was utilized. Growth curves were calculated in three models: 1) the entire sample size, irrespective of conditions, 2) split into conditions as the main effect, and 3) split into conditions and measured across time

for the interaction.

4.9 Effect Sizes and Power Analysis

While researchers often only report p values to indicate statistical significance, this can be a limitation. Further, effect sizes are typically not reported unless the p values are significant. P values depend to some degree on standard error; a larger sample size decreases standard error and lowers the p value (Altman & Bland, 2005). In fact, a statistically significant p value, according to Tomczak and Tomczak, sometimes “mainly indicates that a huge sample size was used” (2014, p. 20; Bradley & Brand, 2013; Sullivan & Feinn, 2012). P values as such do not indicate the strength of the relationship between the variables (Fritz, Morris, & Richler, 2012). Thus, Tomczak and Tomczak (2014) recommend reporting the effect size estimates alongside null findings.

4.10 Study Challenges and Limitations

The use of HEP as a comparison condition brings study design limitations. Additional remuneration is needed when executing a comparison condition. Using HEP may increase cost and participant obligation in a larger scale study. While acknowledging participant burden present in the intervention and comparison conditions, it is important to note that UUI is not a simple condition and it is unlikely to be treated with an insubstantial intervention. These interventions are equally burdensome and they are clinically recognized strategies. When using MBSR, HEP is the gold standard comparison condition. The advantages and disadvantages of implementing HEP as a comparison condition are summarized in Section 4.12.1.

While MBSR or HEP is increasingly prevalent as a treatment modality for many other conditions, it is important to note that this study is only generalizable to those willing and able to participate.

Recruitment in clinical intervention studies is always a challenge. I recruited through multiple sources and modalities. This included a need for a second IRB application associated with a separate sampling source outside the university. Having postmenopausal status as a requirement limited my recruitment yet provided me with potential participants in the needed age range. As this is a pilot feasibility study, I anticipated a small sample size and hypothesis testing was directed as an exploratory aim.

4.11 References

- Altman, D. G., & Bland, J. M. (2005). Standard deviations and standard errors. *BMJ*, 331(7521), 903. doi:10.1136/bmj.331.7521.903
- Arain, M., Campbell, M. J., Cooper, C. L., & Lancaster, G. A. (2010). What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Medical Research Methodology*, 10, 67. doi:10.1186/1471-2288-10-67
- Bandura, A. (2006). Guide for constructing self-efficacy scales. In *Self-efficacy beliefs of adolescents* (pp. 307-337). Charlotte, NC: Information Age Publishing.
- Barnhofer, T., Duggan, D., Crane, C., Hepburn, S., Fennell, M., & Williams, J. M. (2007). Effects of meditation on frontal alpha-asymmetry in previously suicidal individuals. *Neuroreport*, 7(18), 709–712.
- Bellg, A. J., Borrelli, B., Resnick, B., Hecht, J., Minicucci, D. S., Ory, M., . . . Treatment Fidelity Workgroup of the, N. I. H. B. C. C. (2004). Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychology*, 23(5), 443-451. doi:10.1037/0278-6133.23.5.443
- Black, N., Griffiths, J., & Pope, C. (1996). Development of a symptom severity index and a symptom impact index for stress incontinence in women. *Neurourology and Urodynamics*, 15(6), 630-640. doi:10.1002/(SICI)1520-6777(1996)15:6<630::AID-NAU4>3.0.CO;2-G
- Bowen, D. J., Kreuter, M., Spring, B., Cofta-Woerpel, L., Linnan, L., Weiner, D., . . . Fernandez, M. (2009). How we design feasibility studies. *American Journal of Preventive Medicine*, 36(5), 452-457. doi:10.1016/j.amepre.2009.02.002
- Bradley, M. T., & Brand, A. (2013). Alpha values as a function of sample size, effect size, and power: Accuracy over inference. *Psychology Report*, 112(3), 835-844. doi:10.2466/03.49.PR0.112.3.835-844
- Brown, J. S., Bradley, C. S., Subak, L. L., Richter, H. E., Kraus, S. R., Brubaker, L., . . . Diagnostic Aspects of Incontinence Study Research Group. (2006). The sensitivity and specificity of a simple test to distinguish between urge and stress urinary incontinence. *Annals of Internal Medicine*, 144(10), 715-723.
- Brown, J. S., McNaughton, K. S., Wyman, J. F., Burgio, K. L., Harkaway, R., Bergner, D., . . . Girman, C. J. (2003). Measurement characteristics of a voiding diary for use by men and women with overactive bladder. *Urology*, 61(4), 802-809.
- Burgio, K. L., Goode, P. S., Locher, J. L., Umlauf, M. G., Roth, D. L., Richter, H. E., . . . Lloyd, L. K. (2002). Behavioral training with and without biofeedback in the treatment of urge incontinence in older women: A randomized controlled trial. *JAMA*, 288(18), 2293-2299.

- Chan, A. W., Tetzlaff, J. M., Altman, D. G., Laupacis, A., Gotzsche, P. C., Krleza-Jeric, K., . . . Moher, D. (2013). SPIRIT 2013 statement: Defining standard protocol items for clinical trials. *Annals of Internal Medicine*, 158(3), 200-207. doi:10.7326/0003-4819-158-3-201302050-00583
- Cheville, A. L., Kollasch, J., Vandenberg, J., Shen, T., Grothey, A., Gamble, G., & Basford, J. R. (January 01, 2013). A home-based exercise program to improve function, fatigue, and sleep quality in patients with Stage IV lung and colorectal cancer: A randomized controlled trial. *Journal of Pain and Symptom Management*, 45, 5, 811-21.
- Cingi, C., Yorgancioglu, A., Cingi, C. C., Oguzulgen, K., Muluk, N. B., Ulusoy, S., ... Aksoy, M. A. (2015). The "physician on call patient engagement trial" (POPET): Measuring the impact of a mobile patient engagement application on health outcomes and quality of life in allergic rhinitis and asthma patients. *International Forum of Allergy & Rhinology*, 5(6), 487-497.
- Cohen, S., Kamarck, T., & Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior*, 24(4), 385-396. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/6668417>
- Cohen, S., Kessler, R. C., Underwood Gordon, L. (1995). *Measuring stress: A guide for health and social scientists*. New York: Oxford University Press.
- Cohen, S., Williamson, G. (1988). Perceived stress in a probability sample of the United States. In S. Spacapan & S. Oskamp (Eds.), *The social psychology of health*. Newbury Park, CA: Sage Publishers.
- Coyne, K. S., Thompson, C. L., Lai, J. S., & Sexton, C. C. (2015). An overactive bladder symptom and health-related quality of life short-form: Validation of the OAB-q SF. *Neurourology and Urodynamics*, 34(3), 255-263. doi:10.1002/nau.22559
- Coyne, K., Revicki, D., Hunt, T., Corey, R., Stewart, W., Bentkover, J., . . . Abrams, P. (2002). Psychometric validation of an overactive bladder symptom and health-related quality of life questionnaire: The OAB-q. *Quality of Life Research*, 11(6), 563-574.
- Creswell, J. D., Irwin, M. R., Burklund, L. J., Lieberman, M. D., Arevalo, J. M., Ma, J., . . . Cole, S. W. (2012). Mindfulness-based stress reduction training reduces loneliness and pro-inflammatory gene expression in older adults: A small randomized controlled trial. *Brain, Behavior, and Immunity*, 26(7), 1095-1101. doi:10.1016/j.bbi.2012.07.006
- Davidson, R.J., Kabat-Zinn, J., Schumacher, J., Rosenkranz, M., Muller, D., Santorelli, S. F.,... Sheridan, J. F. (2003). Alterations in brain and immune function produced by mindfulness meditation. *Psychosomatic Medicine*, 65(4):564-570.
- Eisendrath, S. J., Gillung, E. P., Delucchi, K. L., Chartier, M., Mathalon, D. H., Sullivan,

- J. C., . . . Feldman, M. D. (2014). Mindfulness-based cognitive therapy (MBCT) versus the health-enhancement program (HEP) for adults with treatment-resistant depression: A randomized control trial study protocol. *BMC Complementary and Alternative Medicine*, 14, 95. doi:10.1186/1472-6882-14-95
- Fritz, C. O., Morris, P. E., & Richler, J. J. (2012). Effect size estimates: Current use, calculations, and interpretation. *Journal of Experimental Psychology: General*, 141(1), 2-18. doi:10.1037/a0024338
- Gallegos, A. M., Lytle, M. C., Moynihan, J. A., Talbot, N. L. (2015). Mindfulness-based stress reduction to enhance psychological functioning and improve inflammatory biomarkers in trauma-exposed women: A pilot study. *Psychological Trauma, Theory, Research, Practice, and Policy*, 7(6), 525-532.
- Gregg, J. A., Callaghan, G. M., Hayes, S. C., Glenn-Lawson, J. L. (2007). Improving diabetes self-management through acceptance, mindfulness, and values: A randomized controlled trial. *Journal of Consulting and Clinical Psychology*, 75(2):336–343.
- Gorman, M. (1999). Development and the rights of older people. In J. Randel et al. (Eds.) *The ageing and development report: Poverty, independence and the world's older people* (pp. 3-21). London: Earthscan Publications Ltd.
- Green, S. B., & Salkind, N. J. (2008). *Using SPSS for Windows and Macintosh: Analyzing and understanding data*. Upper Saddle River, NJ: Pearson Prentice Hall.
- Grossman, P., Niemann, L., Schmidt, S., & Walach, H. (2004). Mindfulness-based stress reduction and health benefits. A meta-analysis. *Journal of Psychosomatic Research*, 57(1), 35-43. doi:10.1016/S0022-3999(03)00573-7
- Hanley, J., Capewell, A., & Hagen, S. (2001). Validity study of the severity index, a simple measure of urinary incontinence in women. *BMJ*, 322(7294), 1096-1097.
- Hildebrand, M. W., Host, H. H., Binder, E. F., Carpenter, B., Freedland, K. E., Morrow-Howell, N., . . . Lenze, E. J. (2012). Measuring treatment fidelity in a rehabilitation intervention study. *American Journal of Physical Medicine and Rehabilitation*, 91(8), 715-724. doi:10.1097/PHM.0b013e31824ad462
- Holroyd-Leduc, J. M., Tannenbaum, C., Thorpe, K. E., & Straus, S. E. (2008). What type of urinary incontinence does this woman have? *JAMA*, 299(12), 1446-1456. doi:10.1001/jama.299.12.1446
- IBM Corp. (2013). IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (1996). *Guidance for industry: E6 good*

clinical practice: Consolidated guidance. Retrieved from <http://purl.access.gpo.gov/GPO/LPS113971>

- Institute of Medicine & Committee on Comparative Effective Research, P. (2009). *Initial national priorities for comparative effectiveness research*. Washington, DC: National Academies Press. Available at www.nap.edu
- Kabat-Zinn, J., Wheeler, E., Light, T., Skillings, A., Scharf, M. J., Cropley, T. G.,... Bernhard, J.D. (1998). Influence of a mindfulness meditation-based stress reduction intervention on rates of skin clearing in patients with moderate to severe psoriasis undergoing phototherapy (UVB) and photochemotherapy (PUVA). *Psychosomatic Medicine*, 60(5), 625–632.
- Kicklighter, J. R. (1991). Characteristics of older adult learners: A guide for dietetics practitioners. *Journal of the American Dietetic Association*, 91(11), 1418-1422.
- Kirshbaum, M. N. (2007). A review of the benefits of whole body exercise during and after treatment for breast cancer. *Journal of Clinical Nursing*, 16, 1, 104-121.
- Kok, B. E., Waugh, C. E., & Fredrickson, B. L. (2013). Meditation and health: The search for mechanisms of action. *Social and Personality Psychology Compass*, 7(1), 27-39.
- Laerd Statistics. (2013). *Repeated measures ANOVA*. Lund Research Ltd. Retrieved from <https://statistics.laerd.com/statistical-guides/repeated-measures-anova-statistical-guide.php>
- Lancaster, G. A., Dodd, S., & Williamson, P. R. (2004). Design and analysis of pilot studies: Recommendations for good practice. *Journal of Evaluation in Clinical Practice*, 10(2), 307-312. doi:10.1111/j.2002.384.doc.x
- Leon, A. C., Davis, L. L., & Kraemer, H. C. (2011). The role and interpretation of pilot studies in clinical research. *Journal of Psychiatric Research*, 45(5), 626-629. doi:10.1016/j.jpsychires.2010.10.008
- Locher, J. L., Goode, P. S., Roth, D. L., Worrell, R. L., & Burgio, K. L. (2001). Reliability assessment of the bladder diary for urinary incontinence in older women. *Journals of Gerontology. Series A: Biological Sciences and Medical Sciences*, 56(1), M32-35.
- Ma, S. H., & Teasdale, J. D. (2004). Mindfulness-based cognitive therapy for depression: Replication and exploration of differential relapse prevention effects. *Journal of Consulting and Clinical Psychology*, 72(1):31–40.
- MacCoon, D. G., Imel, Z. E., Rosenkranz, M. A., Sheftel, J. G., Weng, H. Y., Sullivan, J. C., . . . Lutz, A. (2012). The validation of an active control intervention for mindfulness based stress reduction (MBSR). *Behaviour Research and Therapy*, 50(1), 3-12. doi:10.1016/j.brat.2011.10.011

- McHenry, J. C., Insel, K. C., Einstein, G. O., Vidrine, A. N., Koerner, K. M., & Morrow, D. G. (2015). Recruitment of older adults: Success may be in the details. *Gerontologist*, 55(5), 845-853. doi:10.1093/geront/gns079
- McKinnon, S. P. (2014). *A gentle introduction to growth curves using SPSS*. Nova Scotia, Canada: Dalhousie University. Retrieved from <http://www.slideshare.net/smackinnon/growth-curves-in-spss-a-gentle-introduction>.
- Mirman, D. (n.d.) Growth curve analysis. *Language and cognitive dynamics laboratory*. Philadelphia, PA: Drexel University.
- Mirman, D., Dixon, J. A., & Magnuson, J. S. (2008). Statistical and computational models of the visual world paradigm: Growth curves and individual differences. *Journal of Memory and Language*, 59(4), 475-494.
- Mohr, D. C., Spring, B., Freedland, K. E., Beckner, V., Arean, P., Hollon, S.D., ... Kaplan, R. (2009). The selection and design of control conditions for randomized controlled trials of psychological interventions. *Psychotherapy and Psychosomatics*, 78, 275-284.
- Morin, K. H. (2013). Value of a pilot study. *Journal of Nursing Education*, 52(10), 547-548. doi:10.3928/01484834-20130920-10
- Moore, C. G., Carter, R. E., Nietert, P. J., & Stewart, P. W. (2011). Recommendations for planning pilot studies in clinical and translational research. *Clinical and Translational Science*, 4(5), 332-337. doi: 10.1111/j.1752-8062.2011.00347.x.
- Moynihan, J. A., Chapman, B. P., Klorman, R., Krasner, M. S., Duberstein, P. R., Brown, K. W., & Talbot, N. L. (2013). Mindfulness-based stress reduction for older adults: Effects on executive function, frontal alpha asymmetry and immune function. *Neuropsychobiology*, 68(1), 34-43.
- Munro, B. H. (2005). *Statistical methods for health care research*. Philadelphia, PA: Lippincott, Williams, & Wilkins.
- Murphy, M., Culligan, P. J., Arce, C. M., Graham, C. A., Blackwell, L., & Heit, M. H. (2006). Construct validity of the incontinence severity index. *Neurourology and Urodynamics*, 25(5), 418-423. doi:10.1002/nau.20246
- Nasreddine, Z. S., Phillips, N. A., Bedirian, V., Charbonneau, S., Whitehead, V., Collin, I., . . . Chertkow, H. (2005). The Montreal Cognitive Assessment, MoCA: A brief screening tool for mild cognitive impairment. *Journal of the American Geriatrics Society*, 53(4), 695-699. doi:10.1111/j.1532-5415.2005.53221.x
- National Institute on Aging. (2008). Making your printed health materials senior friendly tips from the National Institute on Aging. Retrieved from <http://memoryworks.org/PUBS/NIA/Making%20Your%20Printed%20Health%20>

Materials%20Senior%20Friendly.pdf

- Nezu, A. M., & Nezu, C. M. (2008). *Evidence-based outcome research: A practical guide to conducting randomized controlled trials for psychological interventions*. New York: Oxford University Press.
- Ospina, M. B., Bond, T. K., Karkhaneh, M., Buscemi, N., Dryden, D. M., Barnes, V., ... Shannahoff-Khalsa, D. (2008). Clinical trials of meditation practices in health care: Characteristics and quality. *Journal of Alternative and Complementary Medicine*, 14, 1199-1214. doi:10.1089/acm.2008.0307.
- Ospina, M. B., Bond, T. K., Karkhaneh, M., Tjosvold, L., Vandermeer, B., Liang, Y., ... Klasen, T. P. (2007). Meditation practices for health: State of the research, (evidence report/technology assessment no. 155). Rockville, MD: Agency for Healthcare Research and Quality, US Department of Health and Human Services.
- Pereira, V. S., e Santos, J. Y. C., Correia, G. N., & Driusso, P. (2011). Tradução e validação para a língua portuguesa de um questionário para avaliação da gravidade da incontinência urinária. *Revista Brasileira De Ginecologia E Obstetricia*, 33(4), 182-187.
- Pett, M. A. (2015). *Nonparametric statistics for health care research*. Washington, DC: SAGE Publishing.
- Pildal, J., Hrobjartsson, A., Jorgensen, K. J., Hilden, J., Altman, D. G., & Gotzsche, P. C. (2007). Impact of allocation concealment on conclusions drawn from meta-analyses of randomized trials. *International Journal of Epidemiology*, 36(4), 847-857. doi:10.1093/ije/dym087
- Potter, D. (n.d.). Palouse mindfulness: Mindfulness-based stress reduction. Retrieved from pages at <http://palousemindfulness.com/>
- Pradhan, E. K., Baumgarten, M., Langenberg, P., Handwerker, B., Gilpin, A. K., Magyari, T., ... Berman, B. M. (2007). Effect of mindfulness-based stress reduction in rheumatoid arthritis patients. *Arthritis and Rheumatism*, 57(7), 1134-1142.
- Pugliese, C. E., & White, S. W. (2014). Brief report: Problem solving therapy in college students with autism spectrum disorders: Feasibility and preliminary efficacy. *Journal of Autism and Developmental Disorders*, 44(3), 719-729. doi:10.1007/s10803-013-1914-8
- Ryan, K. (n. d.) *Patient global impression of improvement*. UK: Physiopedia. Retrieved from [http://www.physio-pedia.com/Patient_Global_Impression_of_Improvement_\(PGI-I\)](http://www.physio-pedia.com/Patient_Global_Impression_of_Improvement_(PGI-I))
- Rohr, G., Christensen, K., Ulstrup, K., & Kragstrup, J. (2004). Reproducibility and validity of simple questions to identify urinary incontinence in elderly women.

- Acta Obstetrica et Gynecologica Scandinavica*, 83(10), 969-972.
doi:10.1111/j.0001-6349.2004.00557.x
- Sandvik, H., Espuna, M., & Hunskaar, S. (2006). Validity of the incontinence severity index: Comparison with pad-weighing tests. *International Urogynecology Journal and Pelvic Floor Dysfunction*, 17(5), 520-524. doi:10.1007/s00192-005-0060-z
- Sandvik, H., Seim, A., Vanvik, A., & Hunskaar, S. (2000). A severity index for epidemiological surveys of female urinary incontinence: Comparison with 48-hour pad-weighing tests. *Neurourology and Urodynamics*, 19(2), 137-145.
- Schulz, K. F., Altman, D. G., Moher, D., & Consort Group. (2010). CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials. *BMC Medicine*, 8, 18. doi:10.1186/1741-7015-8-18
- Specia, M., Carlson, L. E., Goodey, E., & Angen, M. (2000). A randomized, wait-list controlled clinical trial: The effect of a mindfulness meditation-based stress reduction program on mood and symptoms of stress in cancer outpatients. *Psychosomatic Medicine*, 62(5), 613-622.
- Srikrishna, S., Robinson, D., & Cardozo, L. (2010). Validation of the Patient Global Impression of Improvement (PGI-I) for urogenital prolapse. *International Urogynecology Journal*, 21(5), 523-528. doi:10.1007/s00192-009-1069-5
- StataCorp. (2017). *Stata Statistical Software: Release 15*. College Station, TX: StataCorp LLC.
- Sturdy, G., Hillman, D., Green, D., Jenkins, S., Cecins, N., & Eastwood, P. (2003). Feasibility of high-intensity, interval-based respiratory muscle training in COPD. *Chest*, 123(1), 142-150.
- Sullivan, G. M., & Feinn, R. (2012). Using effect size-or why the *p* value is not enough. *Journal of Graduate Medical Education*, 4(3), 279-282. doi:10.4300/JGME-D-12-00156.1
- Tannenbaum, C., Brouillette, J., Korner-Bitensky, N., Dumoulin, C., Corcos, J., Tu, L. M., . . . Valiquette, L. (2008). Creation and testing of the geriatric self-efficacy index for urinary incontinence. *Journal of the American Geriatrics Society*, 56(3), 542-547. doi:10.1111/j.1532-5415.2007.01572.x
- Tannenbaum, C., Brouillette, J., Michaud, J., Korner-Bitensky, N., Dumoulin, C., Corcos, J., . . . Valiquette, L. (2009). Responsiveness and clinical utility of the geriatric self-efficacy index for urinary incontinence. *Journal of the American Geriatrics Society*, 57(3), 470-475. doi:10.1111/j.1532-5415.2008.02146.x
- Tannenbaum, C., Dumolin, C., Korner-Bitensky, N., Corcos, J. and Members of the Axe Incontinence RQR V³. *Development of the Geriatric Self-Efficacy Index for Urinary Incontinence*. 97. Retrieved from

- <https://www.ics.org/Abstracts/Publish/43/000097.pdf>
- Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L. P., . . . Goldsmith, C. H. (2010). A tutorial on pilot studies: The what, why and how. *BMC Medical Research Methodology*, 10, 1. doi:10.1186/1471-2288-10-1
- Tickle-Degnen, L. (2013). Nuts and bolts of conducting feasibility studies. *American Journal of Occupational Therapy*, 67(2), 171-176. doi:10.5014/ajot.2013.006270
- Tomczak, M., & Tomczak, E. (2014). The need to report effect size estimates revisited. An overview of some recommended measures of effect size. *TRENDS in Sport Sciences*, 1(21), 19-25.
- Twiss, C., Triaca, V., Anger, J., Patel, M., Smith, A., Kim, J. H., . . . Rodriguez, L. V. (2009). Validating the incontinence symptom severity index: A self-assessment instrument for voiding symptom severity in women. *Journal of Urology*, 182(5), 2384-2391. doi:10.1016/j.juro.2009.07.025
- U.S. Department of Health and Human Services. (April 1996). Guidance for industry E6 Good Clinical Practice: Consolidated guidance. Rockville, MD: Centers for Biologics Evaluation and Research.
- Van den Broeck, J., Cunningham, S. A., Eeckels, R., & Herbst, K. (2005) Data cleaning: Detecting, diagnosing, and editing data abnormalities. *PLoS Medicine*, 2(10), 966-970.
- Wesson, J., Clemson, L., Brodaty, H., Lord, S., Taylor, M., Gitlin, L., & Close, J. (2013). A feasibility study and pilot randomised trial of a tailored prevention program to reduce falls in older people with mild dementia. *BMC Geriatrics*, 13, 89. doi:10.1186/1471-2318-13-89
- White, K. S., Allen, L. B., Barlow, D. H., Gorman, J. M., Shear, M. K., & Woods, S. W. (2010). Attrition in a multicenter clinical trial for panic disorder. *Journal of Nervous and Mental Disease*, 198(9), 665-671. doi:10.1097/NMD.0b013e3181ef3627
- Willett, J. B., & Bub, K. L. (2005). Latent growth curve analysis. In D. Rindskopf (Ed.), *Encyclopedia of statistics in behavioral science (2nd ed.)*. Oxford, England: Wiley.
- Wood, L., Egger, M., Gluud, L. L., Schulz, K. F., Juni, P., Altman, D. G., . . . Sterne, J. A. (2008). Empirical evidence of bias in treatment effect estimates in controlled trials with different interventions and outcomes: Meta-epidemiological study. *BMJ*, 336(7644), 601-605. doi:10.1136/bmj.39465.451748.AD
- World Health Organization. (2005). *Handbook for good clinical research practice (GCP): Guidance for implementation*. Geneva, Switzerland: World Health Organization.

Yalcin, I., & Bump, R. (2003). Validation of two global impression questionnaires for incontinence. *American Journal of Obstetrics and Gynecology*, 189, 98-101.

4.12 Supplemental Information

4.12.1 Rationale for Choosing HEP Comparison Condition

Table 3 Rationale for Choosing HEP Comparison Condition.

Study design options: MBSR vs -	Advantages	Disadvantages
No control condition (single arm)	<ul style="list-style-type: none"> • Easier recruitment • Less expensive intervention • Less difficult recruitment (no randomization) • Potentially better retention rates as there is no question about which intervention is the “real” one 	<ul style="list-style-type: none"> • Carries less weight • Potential positive differences measured could be explained by alternate justifications (e.g., social interaction or support) • Unlikely to be published without a comparison condition • Study appears less robust without a comparison condition of the same structure/rigor
Waitlist comparison	<ul style="list-style-type: none"> • All participants eventually receive the actual MBSR treatment • Same instructor for all participants • Improves adherence • Reduces attrition (MacCoon et al., 2012) 	<ul style="list-style-type: none"> • Control only; no actual comparison offered to the main intervention • Still a weak study design • Would require as much recruiting/enrolling as using a more vigorous comparison condition • As expensive as the HEP, since all participants will receive intervention • MBSR is already shown to improve mental and physical health <i>compared to waitlist controls</i>, and TAU (Barnhofer et al., 2007; Davidson et al., 2003; Gregg, Callaghan, Hayes, & Glenn-Lawson, 2007; Kabat-Zinn et al., 1998; Ma & Teasdale, 2004; Pradhan et al., 2007; Specia, Carlson, Goodey, & Angen, 2000) • Study appears weaker without a comparison condition of the same structure/rigor • Introduces a number of confounders that make it difficult to accurately interpret the results of meditation research
Unspecified, less time intensive comparison condition	<ul style="list-style-type: none"> • Does not “ask” as much from the comparison condition participants; perhaps carries less ethical concerns as I am not asking for as deep of a time commitment • Still randomized • Probably cheaper 	<ul style="list-style-type: none"> • Not a good comparison condition as the time/ participant investment required is unequal between conditions • Less contact with providers • Less contact with other participants in same condition • Differences between interventions may instead be a result of structural nonequivalencies rather than the mechanism of interest • Possibly different instructor • Study appears feebler without a comparison condition of the same configuration

Table 3 Continued

Study design options: MBSR vs -	Advantages	Disadvantages
Health Enhancement Program	<ul style="list-style-type: none"> • Structurally equivalent to MBSR (number and duration of sessions, therapist training and qualifications, format of the therapy [i.e., condition], and the ability of participants to discuss their particular problems) (MacCoon et al., 2012) • Validated instrument (MacCoon et al., 2012) • Provides a necessary foundation for providing rigorous investigation of relative efficacy of MBSR (arguably not applicable as my study is primarily a feasibility study) • Answers NIH's 2008 call to provide comparison condition to MBSR studies that is of equivalent commitment and experience (Ospina et al., 2008) • Active control which remains inert to mindfulness • While it is a substantial commitment to ask from participants, it is still "equivalent" to the MBSR commitment • Delivers "skillful provision of common therapeutic elements" so as to not bias tests of intervention effects (Mohr et al., 2005) • Includes all nonspecific factors present in MBSR • Designed to match MBSR in 1) positive expectations of success by teacher and participant, 2) an ongoing relationship between teacher and participant, 3) a conceptual framework supporting participant's actions, 4) specific actions and instructions for participant to follow (Kok et al., 2013) • Provides plausible alternative for success through therapeutic rationale 	<ul style="list-style-type: none"> • Substantial (even intense) commitment from participants • Makes future intervention design and accompanying funding less likely as it reduces scalability • Moving forward to full RCT will be difficult due to considerations of cost and participant commitment • Additional compensation needed to remunerate participants • Different instructor

4.12.2 Curricula Comparison of Mindfulness-Based Stress Reduction and Health Enhancement Program

Table 4 Curricula Comparison of Mindfulness-Based Stress Reduction
and Health Enhancement Program

Session (weekly)	MBSR content	HEP content
1 Week 1	<p><i>Simple Awareness</i></p> <p>History of MBSR; Overview of MBSR in science and medical research; Risks and benefits; Guided mindful eating exercise; Guided Body Scan meditation</p>	<p><i>Physical Activity/ Functional Movement and Music Therapy</i></p> <p>Problems in Improving Health: Focuses on physical fitness, functional movement exercises, and music and imagery</p>
2 Week 2	<p><i>Attention and the Brain</i></p> <p>Guided body scan meditation; Guided introduction to sitting meditation; Role of perception and conditioning in the appraisal and assessment of stress</p>	<p><i>Physical Activity/ Functional Movement and Music Therapy</i></p> <p>Physical Activity to Enhance Well-being: Physical activities focus on posture and alignment as ways to optimize function</p>
3 Week 3	<p><i>Dealing with Thoughts</i></p> <p>Guided body awareness and mindful movement practice and guided seated meditation practice; Guided body awareness and mindful movement practice; Guided seated meditation; Guided discussion regarding the tendency of the mind to label events as pleasant or unpleasant instead of staying present to the experience nonconceptually.</p>	<p><i>Nutrition</i></p> <p>Understanding Dietary Guidelines: Participants engage in a lecture and discussion series about basic nutrition principles; diet journaling is reviewed and demonstrated as a way to better understand healthy food choices</p>
4 Week 4	<p><i>Stress: Responding vs. Reacting</i></p> <p>Guided preparatory body awareness and mindful movement practice and guided seated meditation practice; Continued guided discussion regarding the tendency of the mind to label events as pleasant or unpleasant instead of staying present to the experience nonconceptually</p>	<p><i>Nutrition</i></p> <p>Fine-tuning Dietary Choices: Participants learn the use of the USDA My Pyramid Food Tracker Program and behavioral changes are discussed as a way to meet dietary goals</p>

Table 4 Continued

Session (weekly)	MBSR content	HEP content
5 Week 5	<i>Dealing with Difficult Emotions/Sensations</i> Guided sitting meditation and walking meditation; Skill means of working with observed stress reactivity	<i>Physical Activity/ Functional Movement and Music Therapy</i> Adapting to an Unpredictable Environment - Part I: Activities focus on functional movement and alignment; supportive music imagery focuses on responding to the environment in creative ways
6 Week 6	<i>Mindfulness and Communication</i> Guided sitting meditation practices; Guidance through assertive communications strategies	<i>Physical Activity/ Functional Movement and Music Therapy</i> Adapting to an Unpredictable Environment - Part II: Activities such as walking, jogging, and stretching are discussed as participants are encouraged to respond to the environment in creative ways to enhance well-being
7 (6b: Retreat between weeks 6 and 7)	In this <i>day-long session</i> , the learner will deepen the various mindfulness practices, and strengthen the flexible capacity to utilize mindfulness in multiple real-life situations	<i>Spa Day</i> work with all practices, group discussion and exercises
8 Week 7	<i>Mindfulness and Compassion</i> Guided body awareness and mindful movement; Guided sitting meditation focusing on the observation of thoughts	<i>Physical Activity/ Functional Movement and Music Therapy</i> Responding to the Environment in Creative Ways: Participants learn the kinetic chain of functional movement and build group cohesion through group songwriting exercises
9 Week 8	<i>Conclusion</i> Guided body scan meditation, guided sitting meditation	<i>Physical Activity and Functional Movement</i> Support for Continuing Practice: Participants review the course and plan for maintaining gains including all components of HEP

4.12.3 Incontinence Severity Index (ISI)

Participant ID: _____ Date: _____

Please answer the following 2 questions.

1. How often do you experience urinary leakage? (Please check **one**)

___ Never, I do not leak urine

___ Less than once a month

___ A few times a month

___ A few times a week

___ Every day and/or night

2. How much urine do you lose each time? (Please check **one**)

___ None, I do not leak urine

___ Drops

___ Small Splashes

___ More

Thank you for answering these questions.

4.12.4 Incontinence Questions

How can I know what type of incontinence I have? To assess your bladder problems, you can ask yourself the following questions:

1. During the last 3 months, have you leaked urine (even a small amount)?

☐ Yes (continue to question 2) ☐ No (done – no urge incontinence)

2. During the last 3 months, did you leak urine:

(Check all that apply)

☐ When you performing some physical activity, such as coughing, sneezing, lifting or exercise?

☐ When you had the urge or the feeling that you needed to empty your bladder, but you could not get to the toilet fast enough?

☐ Without physical activity and without a sense of urgency?

3. During the last 3 months, did you leak urine *most often*:

(Check only one)

☐ When you performing some physical activity, such as coughing, sneezing, lifting or exercise?

☐ When you had the urge or the feeling that you needed to empty your bladder, but you could not get to the toilet fast enough?

☐ Without physical activity and without a sense of urgency?

☐ About equally as often with physical activity as with a sense of urgency?

Response to #3 Type of Incontinence

Most often with physical activity *Stress only or mostly stress*

Most often with the urge to urinate *Urge only or mostly urge*

Without activity or urgency	<i>Other cause</i>
About equally with activity and urge	<i>Mixed</i>

4.12.5 Montreal Cognitive Assessment and Instructions

MONTREAL COGNITIVE ASSESSMENT (MOCA)
Version 7.1 Original Version

NAME : _____
Education : _____
Sex : _____ Date of birth : _____
DATE : _____

VISUOSPATIAL / EXECUTIVE		POINTS	
		Copy cube <input type="checkbox"/>	Draw CLOCK (Ten past eleven) (3 points) <input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Contour	<input type="checkbox"/> Numbers
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Hands	<input type="checkbox"/> /5
NAMING		POINTS	
			<input type="checkbox"/> /3
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MEMORY		POINTS	
Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.	FACE VELVET CHURCH DAISY RED	1st trial	No points
2nd trial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ATTENTION		POINTS	
Read list of digits (1 digit/ sec.). Subject has to repeat them in the forward order.	<input type="checkbox"/> 2 1 8 5 4	<input type="checkbox"/>	<input type="checkbox"/> /2
Subject has to repeat them in the backward order.	<input type="checkbox"/> 7 4 2	<input type="checkbox"/>	<input type="checkbox"/>
Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors.	<input type="checkbox"/> FBACMNAAJKLBAFAKDEAAAJAMOFAB	<input type="checkbox"/>	<input type="checkbox"/> /1
Serial 7 subtraction starting at 100	<input type="checkbox"/> 93	<input type="checkbox"/> 86	<input type="checkbox"/> 79
4 or 5 correct subtractions: 3 pts, 2 or 3 correct: 2 pts, 1 correct: 1 pt, 0 correct: 0 pt	<input type="checkbox"/> 72	<input type="checkbox"/> 65	<input type="checkbox"/> /3
LANGUAGE		POINTS	
Repeat : I only know that John is the one to help today.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> /2
The cat always hid under the couch when dogs were in the room.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fluency / Name maximum number of words in one minute that begin with the letter F	<input type="checkbox"/> _____ (N ≥ 11 words)	<input type="checkbox"/>	<input type="checkbox"/> /1
ABSTRACTION		POINTS	
Similarity between e.g. banana - orange = fruit	<input type="checkbox"/> train - bicycle	<input type="checkbox"/> watch - ruler	<input type="checkbox"/> /2
DELAYED RECALL		POINTS	
Has to recall words WITH NO CUE	FACE VELVET CHURCH DAISY RED	<input type="checkbox"/>	<input type="checkbox"/> /5
Category cue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Multiple choice cue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Optional		POINTS	
Date	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Month	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Place	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
City	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> /6
© Z.Nasreddine MD	www.mocatest.org	Normal ≥ 26 / 30	TOTAL
Administered by: _____	Add 1 point if ≤ 12 yr edu	<input type="checkbox"/>	<input type="checkbox"/> /30

Copyright Z. Nasreddine MD. Reproduced with permission. Copies are available at

www.mocatest.org .

Montreal Cognitive Assessment (MoCA)

Administration and Scoring Instructions

The Montreal Cognitive Assessment (MoCA) was designed as a rapid screening instrument for mild cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation. Time to administer the MoCA is approximately 10 minutes. The total possible score is 30 points; a score of 26 or above is considered normal.

1. Alternating Trail Making:

Administration: The examiner instructs the subject: *"Please draw a line, going from a number to a letter in ascending order. Begin here [point to (1)] and draw a line from 1 then to A then to 2 and so on. End here [point to (E)]."*

Scoring: Allocate one point if the subject successfully draws the following pattern:

1 -A- 2- B- 3- C- 4- D- 5- E, without drawing any lines that cross. Any error that is not immediately self-corrected earns a score of 0.

2. Visuoconstructional Skills (Cube):

Administration: The examiner gives the following instructions, pointing to the cube: *"Copy this drawing as accurately as you can, in the space below"*.

Scoring: One point is allocated for a correctly executed drawing.

- Drawing must be three-dimensional
- All lines are drawn
- No line is added
- Lines are relatively parallel and their length is similar (rectangular prisms are accepted)

A point is not assigned if any of the above-criteria are not met.

3. Visuoconstructional Skills (Clock):

Administration: Indicate the right third of the space and give the following instructions: *"Draw a clock. Put in all the numbers and set the time to 10 past 11"*.

Scoring: One point is allocated for each of the following three criteria:

- Contour (1 pt.): the clock face must be a circle with only minor distortion acceptable (e.g., slight imperfection on closing the circle);
- Numbers (1 pt.): all clock numbers must be present with no additional numbers; numbers must be in the correct order and placed in the approximate quadrants on the clock face; Roman numerals are acceptable; numbers can be placed outside the circle contour;
- Hands (1 pt.): there must be two hands jointly indicating the correct time; the hour hand must be clearly shorter than the minute hand; hands must be centred within the clock face with their junction close to the clock centre.

A point is not assigned for a given element if any of the above-criteria are not met.

4. Naming:

Administration: Beginning on the left, point to each figure and say: *"Tell me the name of this animal"*.

Scoring: One point each is given for the following responses: (1) lion (2) rhinoceros or rhino (3) camel or dromedary.

5. Memory:

Administration: The examiner reads a list of 5 words at a rate of one per second, giving the following instructions: *"This is a memory test. I am going to read a list of words that you will have to remember now and later on. Listen carefully. When I am through, tell me as many words as you can remember. It doesn't matter in what order you say them"*. Mark a check in the allocated space for each word the subject produces on this first trial. When the subject indicates that (s)he has finished (has recalled all words), or can recall no more words, read the list a second time with the following instructions: *"I am going to read the same list for a second time. Try to remember and tell me as many words as you can, including words you said the first time."* Put a check in the allocated space for each word the subject recalls after the second trial.

At the end of the second trial, inform the subject that (s)he will be asked to recall these words again by saying, *"I will ask you to recall those words again at the end of the test."*

Scoring: No points are given for Trials One and Two.

6. Attention:

Forward Digit Span: Administration: Give the following instruction: *"I am going to say some numbers and when I am through, repeat them to me exactly as I said them"*. Read the five number sequence at a rate of one digit per second.

Backward Digit Span: Administration: Give the following instruction: *"Now I am going to say some more numbers, but when I am through you must repeat them to me in the backwards order."* Read the three number sequence at a rate of one digit per second.

Scoring: Allocate one point for each sequence correctly repeated, (N.B.: the correct response for the backwards trial is 2-4-7).

Vigilance: Administration: The examiner reads the list of letters at a rate of one per second, after giving the following instruction: *"I am going to read a sequence of letters. Every time I say the letter A, tap your hand once. If I say a different letter, do not tap your hand"*.

Scoring: Give one point if there is zero to one errors (an error is a tap on a wrong letter or a failure to tap on letter A).

Serial 7s: Administration: The examiner gives the following instruction: “Now, I will ask you to count by subtracting seven from 100, and then, keep subtracting seven from your answer until I tell you to stop.” Give this instruction twice if necessary.

Scoring: This item is scored out of 3 points. Give no (0) points for no correct subtractions, 1 point for one correction subtraction, 2 points for two-to-three correct subtractions, and 3 points if the participant successfully makes four or five correct subtractions. Count each correct subtraction of 7 beginning at 100. Each subtraction is evaluated independently; that is, if the participant responds with an incorrect number but continues to correctly subtract 7 from it, give a point for each correct subtraction. For example, a participant may respond “92 – 85 – 78 – 71 – 64” where the “92” is incorrect, but all subsequent numbers are subtracted correctly. This is one error and the item would be given a score of 3.

7. **Sentence repetition:**

Administration: The examiner gives the following instructions: “I am going to read you a sentence. Repeat it after me, exactly as I say it [pause]: ***I only know that John is the one to help today.***” Following the response, say: “Now I am going to read you another sentence. Repeat it after me, exactly as I say it [pause]: ***The cat always hid under the couch when dogs were in the room.***”

Scoring: Allocate 1 point for each sentence correctly repeated. Repetition must be exact. Be alert for errors that are omissions (e.g., omitting “only”, “always”) and substitutions/additions (e.g., “John is the one who helped today;” substituting “hides” for “hid”, altering plurals, etc.).

8. **Verbal fluency:**

Administration: The examiner gives the following instruction: “Tell me as many words as you can think of that begin with a certain letter of the alphabet that I will tell you in a moment. You can say any kind of word you want, except for proper nouns (like Bob or Boston), numbers, or words that begin with the same sound but have a different suffix, for example, love, lover, loving. I will tell you to stop after one minute. Are you ready? [Pause] Now, tell me as many words as you can think of that begin with the letter F. [time for 60 sec]. Stop.”

Scoring: Allocate one point if the subject generates 11 words or more in 60 sec. Record the subject’s response in the bottom or side margins.

9. **Abstraction:**

Administration: The examiner asks the subject to explain what each pair of words has in common, starting with the example: “Tell me how an orange and a banana are alike”. If the subject answers in a concrete manner, then say only one additional time: “Tell me another way in which those items are alike”. If the subject does not give the appropriate response (fruit), say, “Yes, and they are also both fruit.” Do not give any additional instructions or clarification. After the practice trial, say: “Now, tell me how a train and a bicycle are alike”. Following the response, administer the second trial, saying: “Now tell me how a ruler and a watch are alike”. Do not give any additional instructions or prompts.

Scoring: Only the last two item pairs are scored. Give 1 point to each item pair correctly answered. The following responses are acceptable:

Train-bicycle = means of transportation, means of travelling, you take trips in both;

Ruler-watch = measuring instruments, used to measure.

The following responses are **not** acceptable: Train-bicycle = they have wheels; Ruler-watch = they have numbers.

10. **Delayed recall:**

Administration: The examiner gives the following instruction: *"I read some words to you earlier, which I asked you to remember. Tell me as many of those words as you can remember."* Make a check mark (✓) for each of the words correctly recalled spontaneously without any cues, in the allocated space.

Scoring: Allocate 1 point for each word recalled freely without any cues.

Optional:

Following the delayed free recall trial, prompt the subject with the semantic category cue provided below for any word not recalled. Make a check mark (✓) in the allocated space if the subject remembered the word with the help of a category or multiple-choice cue. Prompt all non-recalled words in this manner. If the subject does not recall the word after the category cue, give him/her a multiple choice trial, using the following example instruction, *"Which of the following words do you think it was, NOSE, FACE, or HAND?"*

Use the following category and/or multiple-choice cues for each word, when appropriate:

FACE:	<u>category cue:</u> part of the body	<u>multiple choice:</u> nose, face, hand
VELVET:	<u>category cue:</u> type of fabric	<u>multiple choice:</u> denim, cotton, velvet
CHURCH:	<u>category cue:</u> type of building	<u>multiple choice:</u> church, school, hospital
DAISY:	<u>category cue:</u> type of flower	<u>multiple choice:</u> rose, daisy, tulip
RED:	<u>category cue:</u> a colour	<u>multiple choice:</u> red, blue, green

Scoring: No points are allocated for words recalled with a cue. A cue is used for clinical information purposes only and can give the test interpreter additional information about the type of memory disorder. For memory deficits due to retrieval failures, performance can be improved with a cue. For memory deficits due to encoding failures, performance does not improve with a cue.

11. **Orientation:**

Administration: The examiner gives the following instructions: *"Tell me the date today"*. If the subject does not give a complete answer, then prompt accordingly by saying: *"Tell me the [year, month, exact date, and day of the week]."* Then say: *"Now, tell me the name of this place, and which city it is in."*

Scoring: Give one point for each item correctly answered. The subject must tell the exact date and the exact place (name of hospital, clinic, office). No points are allocated if subject makes an error of one day for the day and date.

TOTAL SCORE: Sum all subscores listed on the right-hand side. Add one point for an individual who has 12 years or fewer of formal education, for a possible maximum of 30 points. A final total score of 26 and above is considered normal.

4.12.6 Screening Script

Thank you for calling. I'm Katarina Felsted and I'm a full time faculty member in the College of Nursing at the University of Utah. I am also a third year PhD student and the project you have expressed interest in is my dissertation research.

Would you be so kind to let me know where you heard about my project? [Note information for recruitment tracking]

My research focus is using integrative or alternative therapies to treat chronic conditions in older adults. I am conducting a study using two types of complementary integrative therapies to treat urge urinary incontinence in older adult women.

Does this sound like something you may be interested in?

[If No:] Thank you so much for your time. You are more than welcome to pass my number along to someone else you think may be interested and they can call me.

[Yes: continue below]

This study will randomize participants into one of two groups. Both groups will meet for about two hours a week, for eight weeks. During week six, there will also be a half-day education retreat. These groups are educational and behavioral in nature; we will not be administering any type of medication and we will not be drawing any labs.

We will meet each time at the College of Nursing on the University of Utah campus, and I will provide you with parking validations or public transportation passes, whichever suits you best.

You will also receive a \$100 gift card as compensation for your time [can clarify \$40 after retreat and \$60 after completion of study measures if asked].

You can stop the study at any time. You are not obligated to attend or finish. You may or may not receive any direct benefit from participation. These types of studies are important to move our understanding of incontinence in older women forward.

I will be at every session each week, and I'll be checking in with you every so often during the intervention.

I would like to go through the eligibility criteria with you. I will list the item and you can let me know if you have any questions about it. Then we will move on to the next.

[read each eligibility criterion]

Can I help explain any of those further?

Are there other approaches you have tried in managing your UUI?

I also have a list of exclusion criteria that I would like to go through with you. These may exclude you from participating. Please stop me at any time if you have a question.

[read each exclusion criterion]

Do you have any questions about any of these items?

That's wonderful. I would like to schedule an enrollment interview with you. At that time, I will review the informed consent document, explain which group you will be selected to participate in, your compensation, and answer any questions you may have.

Will you be driving or taking public transportation?

I will send you an address and directions. You have my phone number and are welcome to call me any time. I will meet you at the trax stop/ bus stop/ parking garage and show you how to find the building. Our meeting will take about an hour. I look forward to seeing you!

What day and time is convenient for you in the next few days? May I have your

permission to leave messages on your voice mail, or do you prefer texting?

[obtain contact information (all phones and email), set appointment, send directions
(include phone number again)]

4.12.7 Group Guidelines

- I want a safe class to share my feelings and experiences; therefore, I promise **confidentiality**. I will not use names or identifying information of other class members in discussions outside of this class.
- I understand the importance of **consistency**; therefore, I will attend each class.
- I want my class to **start and end on time**; therefore, I will come on time and leave when the class is over.
- I understand that this is a closed class and **will not bring friends or relatives** with me.
- I recognize that my needs are important and in this class **I have an opportunity to learn and share**.
- **I will allow others their feelings** and listen with caring and trust in their process. Everyone's experience is unique and important.
- I grow best when I'm present for myself; therefore, **I will not use alcohol or drugs** before class.
- I understand that **all faiths and beliefs are honored** in this class.

After, K. P. Supiano, 2015

Grief Support Group Manual, University of Utah-College of Nursing

M. Caserta, personal communication, 20 June 2016

4.12.8 Demographics Questionnaire

Thank you for providing the following data. Please mark each item clearly.

Participant ID _____ Date _____

1. What is your date of birth? _____

(month, date, year)

2. Are you

☐ Single

☐ Married, or living as married

☐ Separated

☐ Divorced

☐ Widowed

3. Please indicate your race/ ethnicity:

☐ American Indian or Alaska Native

☐ Asian

☐ Black or African American

☐ Hispanic or Latina

☐ Native Hawaiian or Other Pacific Islander

☐ White

4. Please indicate your height _____ feet _____ inches
5. Please indicate your weight _____ lbs
6. What is the highest degree or level of school you have completed?
- ☐ None
 - ☐ Kindergarten – 8th grade
 - ☐ Some high school, no diploma
 - ☐ High school graduate or the equivalent (such as GED)
 - ☐ Some college, no degree
 - ☐ Trade/ technical/ vocational training
 - ☐ Associate degree
 - ☐ Bachelor's degree
 - ☐ Master's degree
 - ☐ Doctorate degree
7. Have you ever been pregnant?
- ☐ Yes
 - ☐ No
- If yes, how many deliveries have you had? _____
8. Please indicate age at onset of menopause: _____ years
9. How long have you had urge urinary incontinence symptoms? _____ years _____

months

10. Are you generally satisfied with life? ☐ Yes ☐ No

11. Are you currently dealing with major family or life stressor such as job loss, death, divorce, chronic illness, recent hospitalization? ☐ Yes ☐ No

12. Are you currently being treated for any of the following medical conditions?

a) High blood pressure ☐ Yes ☐ No

b) Diabetes ☐ Yes ☐ No

c) Cancer ☐ Yes ☐ No

d) Heart problems ☐ Yes ☐ No

e) Major depression ☐ Yes ☐ No

f) Anxiety disorder ☐ Yes ☐ No

13. How many different prescription medications, not including vitamins, are you currently taking? _____

14. Please indicate if you are taking medication for:

☐ antidepressants or medication for depression or anxiety

☐ medication for sleep

☐ medication for pain management

☐ beta-blockers for heart disease

4.12.9 Study Measures Overview

Table 5 Study Measures Overview

Component	Measure	Time of measurement
Demographics	Standard demographic questionnaire	At baseline; caffeine and medication use will also be recorded again at completion
<i>Research Feasibility</i>		
Recruitment	Number enrolled (% of contacted); from where/how recruited; also document why those who didn't enroll chose not to	During recruitment phase
Retention	Number who completed intervention; document attrition reasons if given	Tracked from time of consent through completion of study
Treatment Fidelity	Treatment integrity objectives met	After each session in a brief meeting with the interventionist At completion of study with a checklist filled out by participants
<i>Intervention Feasibility</i>		
Acceptability	+ vs - response, verbal approach and recorded feedback	After each session of treatment condition and comparison condition with randomly selected participants
Tolerability	Drop out count, open ended exit interview	Evaluated from beginning of study through study completion
Treatment Adherence	Attendance and homework completion	At each session of treatment condition and comparison condition, measured by interventionist
<i>Preliminary Efficacy</i>		
Symptom Severity (Outcome Measure)	Incontinence Severity Index Part 1 of Overactive Bladder Questionnaire Short Form (Q1-6)	At baseline and at study completion, by participant
Symptom Bother (Outcome Measure)	Overactive Bladder Questionnaire Short Form Overall and Part 2 (HRQL) specifically	At baseline and at study completion, by participant
Perceived Stress (Outcome Measure)	Perceived Stress Scale	At baseline and at study completion, by participant
Perceived Self-efficacy (Outcome Measure)	Geriatric Self-Efficacy Index of Urinary Incontinence	At baseline and at study completion, by participant
Rate and Trajectory of Change (Process Measure)	Patient Global Impression of Improvement (PGI-I)	After each session of treatment and comparison condition, by participant

4.12.10 Overactive Bladder Questionnaire Short Form Symptom

Bother (OAB-q SF)

This questionnaire asks about how much you have been bothered by selected bladder symptoms during the past 4 weeks. Please circle the number that best describes the extent to which you were bothered by each symptom during the past 4 weeks. There are no right or wrong answers. Please be sure to answer every question.

Participant ID _____ Date _____

1 = Not at all. 2 = A little bit. 3 = Somewhat. 4 = Quite a bit. 5 = A great deal.

6 = A very great deal.

During the past 4 weeks, how bothered were you by:

- | | | | | | | |
|---|---|---|---|---|---|---|
| 1. An uncomfortable urge to urinate? | 1 | 2 | 3 | 4 | 5 | 6 |
| 2. A sudden urge to urinate with little or no warning? | 1 | 2 | 3 | 4 | 5 | 6 |
| 3. Accidental loss of small amounts of urine? | 1 | 2 | 3 | 4 | 5 | 6 |
| 4. Nighttime urination? | 1 | 2 | 3 | 4 | 5 | 6 |
| 5. Waking up at night because you had to urinate? | 1 | 2 | 3 | 4 | 5 | 6 |
| 6. Urine loss associated with a strong desire to urinate? | 1 | 2 | 3 | 4 | 5 | 6 |

For the following questions, please think about your overall bladder symptoms in the past 4 weeks and how these symptoms have affected your life. Please answer each question about how often you have felt this way to the best of your ability.

Please answer each question using this scale:

1 = None of the time. 2 = A little of the time. 3 = Some of the time.

4 = A good bit of the time. 5 = Most of the time. 6 = All of the time.

During the past 4 weeks, how often have your bladder symptoms:

1. Caused you to plan “escape routes” to restrooms in public places? 1 2 3 4 5 6
2. Made you feel like there is something wrong with you? 1 2 3 4 5 6
3. Interfered with your ability to get a good night’s rest? 1 2 3 4 5 6
4. Made you frustrated or annoyed about the amount of time you spend in the restroom?
1 2 3 4 5 6
5. Made you avoid activities away from the restroom (i.e., walks, running, hiking)?
1 2 3 4 5 6
6. Awakened you during sleep? 1 2 3 4 5 6
7. Caused you to decrease your physical activities (exercising, sports, etc.)?
1 2 3 4 5 6
8. Caused you to have problems with your partner or spouse? 1 2 3 4 5 6
9. Made you uncomfortable while traveling with others because of needing to stop for a
restroom? 1 2 3 4 5 6
10. Affected your relationships with family and friends? 1 2 3 4 5 6

11. Interfered with getting the amount of sleep you needed? 1 2 3 4 5 6
12. Caused you embarrassment? 1 2 3 4 5 6
13. Caused you to locate the closest restroom as soon as you arrive at a place you have
never been? 1 2 3 4 5 6

4.12.11 Perceived Stress Scale

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate by circling how often you felt or thought a certain way.

Participant ID _____ Date _____

0 = Never 1 = Almost Never 2 = Sometimes 3 = Fairly Often 4 = Very Often

1. In the last month, how often have you been upset because of something that happened unexpectedly?

0 1 2 3 4

2. In the last month, how often have you felt that you were unable to control the important things in your life?

0 1 2 3 4

3. In the last month, how often have you felt nervous and “stressed”?

0 1 2 3 4

4. In the last month, how often have you felt confident about your ability to handle your personal problems?

0 1 2 3 4

5. In the last month, how often have you felt that things were going your way?

0 1 2 3 4

6. In the last month, how often have you found that you could not cope with all the things

that you had to do?	0	1	2	3	4
1. I had to be very careful about what I said and did.					
2. I had to be very careful about who I talked to.					
3. I had to be very careful about where I went.					
4. I had to be very careful about what I ate and drank.					
5. I had to be very careful about who I was around.					
6. I had to be very careful about what I wore.					
7. I had to be very careful about what I did for fun.					
8. I had to be very careful about what I thought.					
9. I had to be very careful about what I felt.					
10. I had to be very careful about what I believed.					
11. I had to be very careful about what I wanted.					
12. I had to be very careful about what I needed.					
13. I had to be very careful about what I should.					
14. I had to be very careful about what I could.					
15. I had to be very careful about what I might.					
16. I had to be very careful about what I would.					
17. I had to be very careful about what I had.					
18. I had to be very careful about what I was.					
19. I had to be very careful about what I am.					
20. I had to be very careful about what I do.					

7. In the last month, how often have you been able to control irritations in your life?

0 1 2 3 4

8. In the last month, how often have you felt that you were on top of things?

0 1 2 3 4

9. In the last month, how often have you been angered because of things that were outside of your control?

0 1 2 3 4

0 1 2 3 4

10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

0 1 2 3 4

0 1 2 3 4

4.12.12 Geriatric Self-Efficacy Scale for Urinary Incontinence (GSE-UI)

4.12.12.1 Study Enrollment Time

Participant ID _____ Date _____

How confident are you that you can hold your urine	0 = Not very confident 10 = Very confident 0 ←-----5-----→ 10
When you are at home and have to go to the bathroom?	0 1 2 3 4 5 6 7 8 9 10
When you are away from home?	0 1 2 3 4 5 6 7 8 9 10
Long enough to get to the bathroom in time during the night?	0 1 2 3 4 5 6 7 8 9 10
For at least 20 minutes when you feel the urge?	0 1 2 3 4 5 6 7 8 9 10
When coughing?	0 1 2 3 4 5 6 7 8 9 10
When sneezing?	0 1 2 3 4 5 6 7 8 9 10
When laughing?	0 1 2 3 4 5 6 7 8 9 10
When you are nervous?	0 1 2 3 4 5 6 7 8 9 10
How confident are you that you can . . .	
Visit places where you may have difficulty locating the bathroom?	0 1 2 3 4 5 6 7 8 9 10
Go out on social outings without worrying about urine loss?	0 1 2 3 4 5 6 7 8 9 10
Prevent urine loss without relying on pads or protection when you are at home?	0 1 2 3 4 5 6 7 8 9 10
Prevent urine loss without relying on pads or protection when you are out?	0 1 2 3 4 5 6 7 8 9 10

Implement the elements of what you will learn to manage your urine control?	0 1 2 3 4 5 6 7 8 9 10
---	------------------------

4.12.12.2 Study Completion Time

Participant ID _____ Date _____

How confident are you that you can hold your urine	0 = Not very confident 10 = Very confident 0 ←-----5-----→ 10
When you are at home and have to go to the bathroom?	0 1 2 3 4 5 6 7 8 9 10
When you are away from home?	0 1 2 3 4 5 6 7 8 9 10
Long enough to get to the bathroom in time during the night?	0 1 2 3 4 5 6 7 8 9 10
When coughing?	0 1 2 3 4 5 6 7 8 9 10
When sneezing?	0 1 2 3 4 5 6 7 8 9 10
When laughing?	0 1 2 3 4 5 6 7 8 9 10
For at least 20 minutes when you feel the urge?	0 1 2 3 4 5 6 7 8 9 10
When you are nervous?	0 1 2 3 4 5 6 7 8 9 10
How confident are you that you can . . .	
Visit places where you may have difficulty locating the bathroom?	0 1 2 3 4 5 6 7 8 9 10
Go out on social outings without worrying about urine loss?	0 1 2 3 4 5 6 7 8 9 10
Prevent urine loss without relying on pads or protection when you are at home?	0 1 2 3 4 5 6 7 8 9 10
Prevent urine loss without relying on pads or protection when you are out?	0 1 2 3 4 5 6 7 8 9 10
Implement the elements of what you have learned to manage your urine control?	0 1 2 3 4 5 6 7 8 9 10

4.12.13 Patient Global Impression of Improvement

Participant ID _____ Date _____

PGI-I: Patient Global Impression of Improvement

Compared to how your urinary control was at admission to the project, do you feel
that you are:

- ☐ Very much better
- ☐ Much better
- ☐ Better
- ☐ About the same
- ☐ Worse
- ☐ Much worse
- ☐ Very much worse

4.12.14 CONSORT Flow Diagram

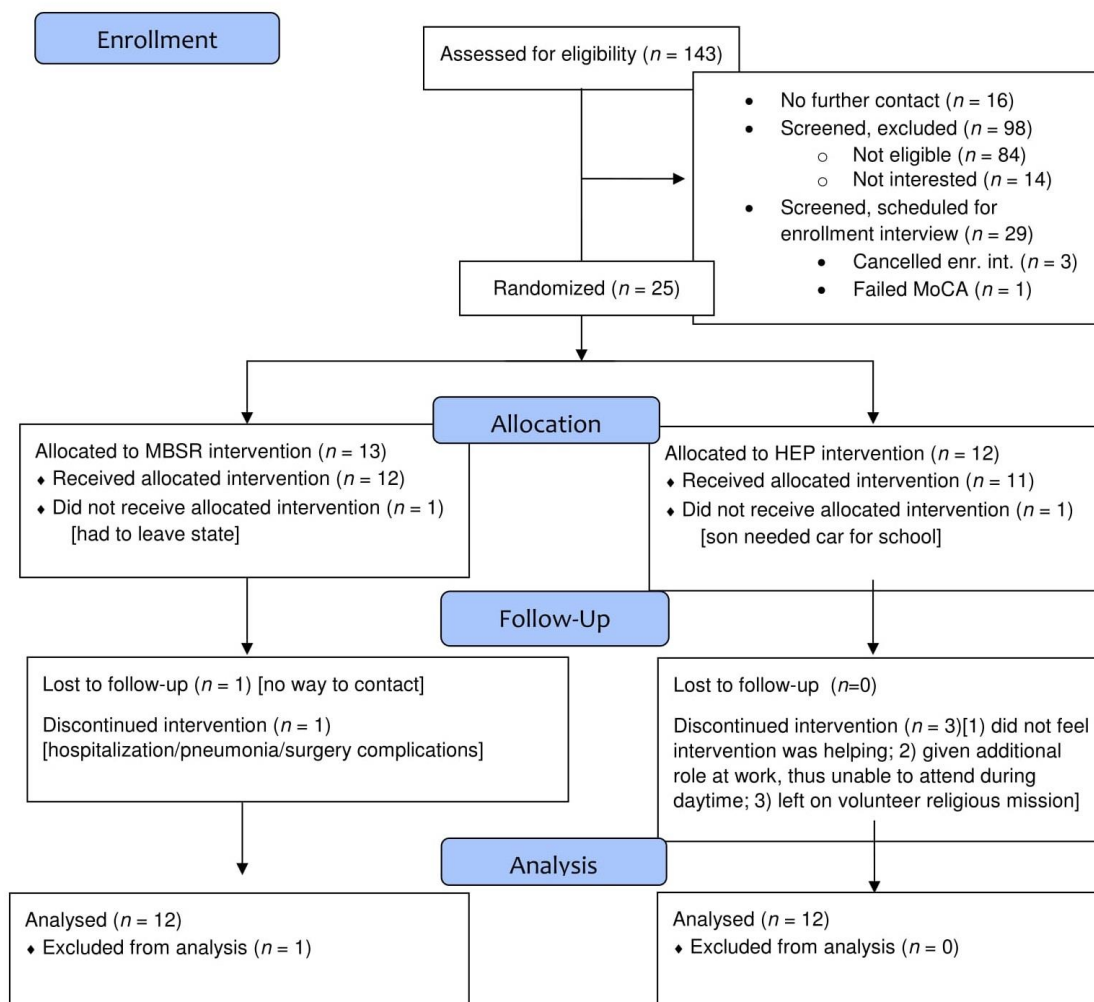


Figure 2 CONSORT Flow Diagram for Comparing Mindfulness-Based Stress Reduction With the Health Enhancement Program in the Treatment of Urge Urinary Incontinence in Older Adult Women (SHUW)

CHAPTER 5

DESIGNING RIGOROUS METHODS IN INTEGRATIVE RESEARCH:
COMPARING MINDFULNESS-BASED STRESS REDUCTION
WITH THE HEALTH ENHANCEMENT PROGRAM IN THE
TREATMENT OF URGE URINARY INCONTINENCE IN
OLDER ADULT WOMEN: A PILOT FEASIBILITY
AND RANDOMIZED CONTROLLED
TRIAL (SHUW)

Katarina Friberg Felsted, MS¹

Katherine Perry Supiano, PhD, LCSW, FT¹

Jia-Wen Guo, PhD, RN¹

5.1 Abstract

Older adult women are marginalized in scientific research. Prior research has been done studying the treatment of urinary urge incontinence through mindfulness-based stress reduction. The highest prevalence of urinary urge incontinence is found in older adult women, yet this is the first study to treat older adult women with urge urinary incontinence with mindfulness-based stress reduction.

A rigorous pilot feasibility and randomized controlled trial is described from study design through follow-up. Preparations, procedures, and execution of the study including measures, data management, and statistical analyses are delineated. Considerations necessary due to the specific population are explained.

Authors discuss significant characteristics, anticipated results, as well as successes and difficulties embedded in the methods used.

5.2 Background

5.2.1 Rationale

Symptoms of urinary leakage with urgency (known as urge urinary incontinence, or UUI) are common, disproportionately affect older women, and can be socially and psychologically devastating. Mindfulness-based stress reduction (MBSR) appears to be a favorable therapy for some women with UUI.^{1,2} The overarching goal of this research was to evaluate potential treatment options for older women with symptoms of UUI, with a specific focus on MBSR, a promising therapeutic approach in preliminary studies and one increasingly used to treat symptoms associated with brain-visceral interactions.^{3,4}

The research protocol described here evaluated the feasibility and preliminary

efficacy of treating UUI in older adult women with MBSR in comparison to the health enhancement program (HEP), a validated educational intervention, through a combined pilot study and randomized controlled trial.⁵ Feasibility studies are an essential step in the translation of evidence-based interventions to broader implementation. Feasibility determinants included both research feasibility (recruitment, retention, treatment fidelity) and intervention feasibility (acceptability, tolerability, treatment adherence). Clinical outcomes to evaluate preliminary intervention efficacy included severity of UUI symptoms, bother of UUI symptoms, perceived stress, and perceived level of self-efficacy of self-management of UUI symptoms. Preliminary efficacy of the intervention was also evaluated.

5.2.2 Hypothesis

The capacity for hypothesis testing, or establishing causal inference may be limited in a pilot study due to insufficient power; however, the information from efficacy testing is vital in informing future larger scale clinical trials.⁶ This study served as a necessary step for the development of effectiveness trials of MBSR in treatment of UUI in older adult women by informing and guiding evaluation, intervention implementation, and dissemination of findings. As this was a pilot feasibility study, a small sample size was anticipated and hypothesis testing was conducted as an exploratory aim.

5.2.3 Objectives

- **Aim 1:** To determine the research feasibility of an RCT comparing MBSR and HEP in older adult women presenting with UUI, measured by recruitment,

retention, and treatment fidelity.

- **Aim 2:** To determine the intervention feasibility of an RCT comparing MBSR and HEP implementation in older adult women presenting with UII, measured by acceptability, tolerability, and treatment adherence.
- **Exploratory aim:** To evaluate short term preliminary efficacy of MBSR for treatment of UII in older adult women, in comparison to HEP, measured by symptom severity, symptom bother, perceived stress, perceived self-efficacy, and the trajectory of change.

5.3 Methods

5.3.1 Study Design

Participants were recruited from the university health care system as well as from select places in the community. They were consented, enrolled, randomized and then outcome measures were administered at the enrollment to have baseline data. Participants participated in one of two treatment conditions, and weekly process measures were administered throughout each week. At completion of the intervention conditions, the outcome measures that had been administered at enrollment were once again administered. See Figure 3.

5.3.2 Procedures

These procedures are individually outlined below.

5.3.2.1 Recruitment

Recruitment of older adults carries particular challenges and can be improved by cultivating relationships with community-based organizations, face-to-face contact with potential study participants, and providing service as an access point to eligible participants.⁷ Pilot sample size should be based on “the pragmatics of recruitment and the necessities for examining feasibility.”⁶ To minimize the risk of embarrassment from participating in the project, the study was advertised as a “Bladder health” study.

Participants were recruited from the University’s Health Care System, including a geriatrics and pelvic disorder clinic, the Osher Lifelong Learning Institute on campus, where older adults attend to learn about a variety of subjects, and two research participant registries within the Health Sciences Center. These areas were utilized for recruitment in prior similar studies and were chosen as locations that would be accessed by older adults. Recruitment also included county senior centers, which necessitated an additional Institutional Review Board application, through the State Department of Health and Human Services. Success rates of various recruitment strategies were tracked.

5.3.2.2 Screening

When potential participants contacted study personnel, the framework of the study, the time commitment, transportation options, and remuneration were explained. For the purposes of transparency and reproducibility, a screening script was followed (see 4.12.6). When the participant expressed interest, the eligibility and exclusion criteria were reviewed (see 4.3.1). When a potential participant qualified for the study, she was invited to come in for an enrollment interview. All qualified participants who were

invited to come in for an interview did so.

5.3.2.2.1 Informed Consent

Potential participants who met the eligibility criteria were provided with an informed consent document, as well as a study summary highlighting the key features in a one-page document. The consent document was reviewed with participants paragraph by paragraph. Participants were informed of the confidentiality guidelines of participation and given a copy of the consent document.

5.3.2.2.2 Enhanced Enrollment

Upon obtaining informed consent, the Montreal Cognitive Assessment⁸ (MoCA) (see 4.12.5) was administered and, as appropriate, administration of the baseline measures proceeded. Enrolled participants were informed of their assigned intervention while preserving the blinded-to-condition nature of the study design.

5.3.2.2.3 Randomization

As outlined in the Consolidated Standards of Reporting Trials (CONSORT),^{9,10} participants were randomized into the MBSR or HEP condition according to the order of enrollment, and randomization was generated through the block method to ensure that enrollment was generated with a 1:1 ratio, with varied block sizes. The PI and the bio-informatician generated the randomization. The randomized allocation was presented in a sealed envelope during enrollment and opened by the consented participant. Participants were blinded to the study condition. This was done to adhere to CONSORT guidelines

and potentially diminish dropout rates in the comparison condition.^{9,10}

5.3.2 Sample

Twenty-five postmenopausal females were recruited as participants into this study. The target range of enrollment was 12-30 participants. This number was chosen to practically achieve meaningful intervention condition size and to be consistent with pilot studies on bio-behavioral interventions delivered in a group format. This range was also recommended by interventionists (Vicki Overfelt, personal communication, November 30, 2016; Amy Stevenson, personal communication, January 17, 2017).

5.3.3 Treatments

The interventionists in these two study conditions were certified and credentialed. Because of the sensitive nature of the UUI condition, female interventionists were hired for both treatment arms.

5.3.3.1 Mindfulness-Based Stress Reduction (MBSR)

Mindfulness-Based Stress Reduction is an 8-week psychosocial intervention delivered in a group setting. Participants attend 9 total sessions, meeting for 2 hours each week for 8 weeks, with a retreat between weeks 6 and 7. Class instruction is augmented by daily home practice, provided to each participant.

5.3.3.2 Health Enhancement Program (HEP) Comparison Condition

The HEP protocol is a substantive active comparison condition, which delivers “skillful provision of common therapeutic elements,”⁵ so as to not bias tests of intervention effects.¹¹ It is credible to both participants and providers and offers a plausible alternative for success through therapeutic rationale. Identical to MBSR in its format, participants meet in 9 sessions, 2 hours a week for 8 weeks, with a retreat between weeks 6 and 7. Class instruction in four basic categories is supplemented with weekly homework, much like the MBSR practice (Table 3).

5.3.3.3 Rationale for Selection of the Comparison Condition

The HEP condition is responsive to the US National Institutes of Health’s call to researchers to provide a comparison condition for MBSR studies that is of equivalent commitment and experience (Table 2).¹²

5.3.4 Assessments

5.3.4.1 Demographics

Demographic collection at baseline included date of birth, race/ethnicity, height and weight to calculate BMI, marital status, education, brief gynecologic and medical history, brief UUI history, medication use, caffeine intake, life satisfaction, and life stress. Caffeine use and medication was recorded again at completion of study, to determine whether or not use remained constant throughout the study.

5.3.4.2 Feasibility Measures

The feasibility measures are divided into research feasibility measures, having to do with research process, and intervention feasibility measures, having to do with participant process and outcome (see 4.12.9).

5.3.4.2.1 Research Feasibility Measures

Recruitment was measured as number of people enrolled, and referral source was noted.¹³ The ratio of contacted to enrolled was also calculated, and reasons for exclusion (by researcher) or declining (by respondent) were recorded.

Retention was measured as percent of enrolled participants completing the study and accounted for reasons for attrition.¹⁴ If a participant did not attend a session, a courteous follow-up telephone call was placed, exploring what the attendance challenge may have been. These data were recorded in field notes and the information was handled as protected data.

Treatment delivery was measured by consulting with the interventionists after each session, to confirm that treatment integrity objectives were met. A 75% or higher achievement on these objectives was considered the standard confirming objectives being met.¹⁵ Treatment delivery was also measured by a checklist given to participants at study completion, to mark those concepts covered in the weekly interventions. A 75% or higher achievement on these participants' reports is typically the standard to confirm the interventionists' concordance with their respective intervention protocols.¹⁵

5.3.4.2.2 *Intervention Feasibility Measures*

Acceptability was measured as a positive versus negative response to the question, “How did it go today?” Following each session, 2 randomly selected participants in each intervention were approached by the PI and assessed on this acceptability question. Each qualitative response was coded quantitatively as a negative or a positive response and the aggregate data was analyzed.

Tolerability was measured as number of dropouts due to stated distress from or dislike of either intervention experience, as opposed to someone needing to withdraw due to a family emergency or illness.^{16,17} Participants who withdrew were asked to respond to a single question, “Help me understand what made this challenging?”

Treatment adherence was measured by attendance and homework completion at each session, as recorded by the interventionists and confirmed by the PI.

5.3.4.3 Preliminary Efficacy Measures

5.3.4.3.1 *Outcome Measures*

The 4 measures of outcome preliminary efficacy, the Incontinence Severity Index (ISI), the Overactive Bladder Questionnaire Short Form (OAB-q SF), the Perceived Stress Scale (PSS), and the Geriatric Self-Efficacy Index for Urinary Incontinence (GSE-UI), were administered at baseline and again at study completion. The ISI and OAB-q were selected from the literature examining UUI. The PSS and the GSE-UI were selected as they were theoretically driven. These measures had to be $\geq 75\%$ completed to be included in data analysis.

5.3.4.3.1.1 *Incontinence Severity Index (ISI). 2-item scale.* The Incontinence

Severity Index^{18,19} is a short, simple, and sensitive measure of severity of urinary incontinence in women with reported Cronbach's α coefficient = 0.93 (see section 4.12.3).

5.3.4.3.1.2 Overactive Bladder Questionnaire Short Form (OAB-q SF). 19 item scale. The Overactive Bladder Questionnaire Short Form²⁰ measures symptom bother as well as severity to some extent on a Likert-type scale from 1 (not at all) to 6 (a very great deal) with higher score relating to higher bother. The OAB-q is able to differentiate between participants with and without overactive bladder incontinence and has reported Cronbach α values ranging from 0.86 to 0.94 (section 4.12.10).

5.3.4.3.1.3 Perceived Stress Scale (PSS-10). 10-item scale. The Perceived Stress Scale²¹⁻²³ measures stress in the last month on a Likert-type scale from 0 (never) to 4 (very often). Scores range from 0 to 40; higher scores relate to higher levels of perceived stress. Cohen and colleagues state that the PSS demonstrates “substantial reliability and validity”²¹ and presented coefficient Reported Cronbach α values were 0.84, 0.85, 0.86 in 3 samples (see Section 4.12.11).²¹

5.3.4.3.1.4 Geriatric Self-Efficacy Index for Urinary Incontinence (GSE-UI). 13 item scale; adapted. The GSE-UI measures self-efficacy with regard to urinary incontinence in 65 and older. The GSE-UI has a sensitivity of 0.75, a specificity of 0.78, and a reported Cronbach's α = 0.90.^{24,25} Scores range from 0 to 130 and responses are recorded on a Likert-type scale from 0 (not confident) to 10 (very confident) (section 4.12.12); higher scores relate to higher levels of self-efficacy.

5.3.4.3.2 *Process Measure*

5.3.4.3.2.1 Patient Global Impression of Improvement (PGI-I). 1-item Scale. To inform a future, larger scale trial, we noted the trajectory of participant-perceived change. Each participant completed a Patient Global Impression of Improvement scale after each session. The PGI-I has been validated specifically in incontinence and that it shows “excellent test-retest reliability.”²⁶ The PGI-I was administered after each of the 9 sessions (see Section 4.12.13).

5.3.5 Follow-up

A 6-month follow-up was scheduled with participants to repeat outcome and process measures. At that time, a semistructured qualitative interview was conducted.

5.3.6 Timetable

The timetable of this study was approximately 1 year. IRB approvals were obtained over a 5-month period. Recruitment and enrollment ensued for 10 weeks. The study itself, with both the treatment and comparison conditions separately receiving the intervention, lasted 8 weeks. Data entry, export, and analysis followed over the next 3 months.

5.3.7 Safety Consideration

All attempts to safeguard confidentiality were made using technological and physical precautions. Participants were assigned a study identification number to maintain a confidential environment. Both the CONSORT^{8,9} and Standard Protocol Items:

Recommendations for Interventional Trials (SPIRIT) guidelines were followed with respect to confidentiality.⁸ In addition, privacy and confidentiality considerations were reviewed with each participant individually at enrollment and in each study condition as discussed by the respective interventionist.⁸

5.3.8 Quality Assurance

Good clinical practices, encompassing research staff training, informed consent procedures, Institutional Review Board (IRB) reporting, and monitoring/oversight procedures of both interventionists and participants, were strictly adhered to in the study.^{27,28}

5.3.9 Data Management

Data were collected in paper form and entered and electronically managed in Research Electronic Data Capture (REDCapTM), a secure, web-based application intended to support data capture for research studies. Data were exported to IBM SPSS version 24.0 and STATA for data analysis.^{29,30}

5.3.10 Statistical Analysis

There were 5 components to the analytic plan: analysis of demographics, research feasibility measures, intervention feasibility measures, outcome measures, and the process measure organized by aims below. Preanalysis of demographic data was conducted. Frequency statistics were recorded.

5.3.10.1 Aim 1

To determine the **research feasibility**, determinants included recruitment, retention, and treatment fidelity.

Data analysis for the *recruitment* and *retention* portions of this aim were performed through descriptive statistics, displayed in a CONSORT flowchart illustrating the number of participants who were screened, met eligibility/exclusion criteria, enrolled, consented, participated, and completed the study (see Section 4.12.14). Data addressing reasons why potential participants were ineligible, why participants were not consented (exclusion and declining), and reasons for participant attrition are described in this flowchart. *Treatment delivery* is considered adequate if the interventionists' observance level equals 75% of scheduled content to be delivered, as evidenced through interventionists' verification and participants' verification of treatment objectives.

5.3.10.2 Aim 2

To determine the **intervention feasibility**, determinants included acceptability, tolerability, and treatment adherence.

Acceptability was counted as positive and negative expression. Participant feedback was documented after each session and reported as a percentage. *Tolerability* was measured as dropout count and reported as a percentage. *Treatment adherence* was measured as a count of attendance and homework completion and reported as percentages.

5.3.10.3 Exploratory Aim

To evaluate short term **preliminary efficacy** outcome measures of symptom severity, symptom bother, perceived stress, perceived self-efficacy, and the process measure of trajectory of change were analyzed using independent samples *t* tests, and when the assumption was not achieved, Mann-Whitney U tests were employed to measure between condition differences. To analyze within condition data paired *t* tests were utilized and in nonparametric instances, the Wilcoxon ranked *t* test was employed.

To analyze the exploratory aim *process* measure, The Patient Global Impression of Improvement, linear mixed effects modeling was utilized. These were calculated in three models: 1) the entire sample size, irrespective of conditions; 2) split into conditions as the main effect; and 3) split into conditions and measured across time for the interaction.

5.3.11 Ethics

All study protocols, recruitment procedures, measures, and instruments were reviewed and approved by the University Institutional Review Board and the Department of Human Services Review Board prior to recruitment. Participants were informed of expectations of privacy and confidentiality. Every effort was taken to preserve the participants' dignity, respect, and autonomy.

5.3.11.1 Compensation

A total \$100 in gift-card compensation was staggered across the study for all participants. Participants who did not complete the study received a prorated amount of

compensation. Public transportation passes and parking validations were provided.

5.4 Discussion

5.4.1 Important Aspects

This is the first study to ever test feasibility and preliminary efficacy of a mindfulness-based stress reduction intervention for urinary urge incontinence (UI) in the older adult population. Additionally, the 2 most marginalized groups in scientific research are women and older adults. These 2 populations are underserved when omitted from scientific research. As the prevalence of UI is highest in older adult women, this was a crucial population to study.

5.4.2 Expected Outcomes

As this is a pilot feasibility study, the expected outcomes revolved around the feasibility of offering an intensive intervention in this age group.

5.4.3 Problems Anticipated

One concern included participants locating the study site. The enrollment interview took place in the same location as the intervention classes to facilitate participant comfort in the logistics of location and parking. A map and instructions for navigation and parking were sent to the participant prior to the study, and the participant was met at the parking garage and escorted to the building where the enrollment interview and study were conducted. This enhanced enrollment procedure facilitated retention.⁶

5.4.4 Limitations

This is a feasibility study with a small sample size with potential for insufficient power to determine treatment effectiveness. Based on recommendations in the literature, the study did not include one arm without any intervention as a real “control” group.¹²

The use of HEP as a comparison condition brought study challenges. Additional remuneration is needed when executing a comparison condition. Using HEP may impact a larger scale study, perhaps increasing cost and participant obligation. When using MBSR, HEP is the gold standard comparison condition. The advantages and disadvantages of implementing HEP as a comparison condition are summarized in Table 2.

Recruitment in clinical intervention studies is a challenge. This potential limitation was mitigated by recruiting across multiple sources and modalities. Having postmenopausal status as a requirement targeted recruitment by limiting the potential pool of respondents to those within the needed age range.

5.5 Conclusion

The delineation of a study protocol for testing a specific population with a precise condition which uses a complementary treatment is useful for those planning future research in similar situations. As this was a pilot feasibility as well as a randomized controlled trial, researchers had to plan a rigorous design, a successful recruitment, and follow strict protocols throughout the year of research in order to ensure scientific rigor. The older adult and female populations, here combined in one group, stand to benefit from inclusion in scientific research.

5.6 Conflicts of Interest

The authors report no conflict of interest.

5.7 Acknowledgments

The authors are grateful for several funding sources which enabled this research to be conducted:

- University of Utah College of Nursing Noorda-Hartford Fellowship
- University of Utah Office of the Associate Vice President for Health Equity and Inclusion
- Sigma Theta Tau International Gamma Rho Chapter.

5.8 Trial Registry

Registered with Clinical Trials.gov, NCT03176901

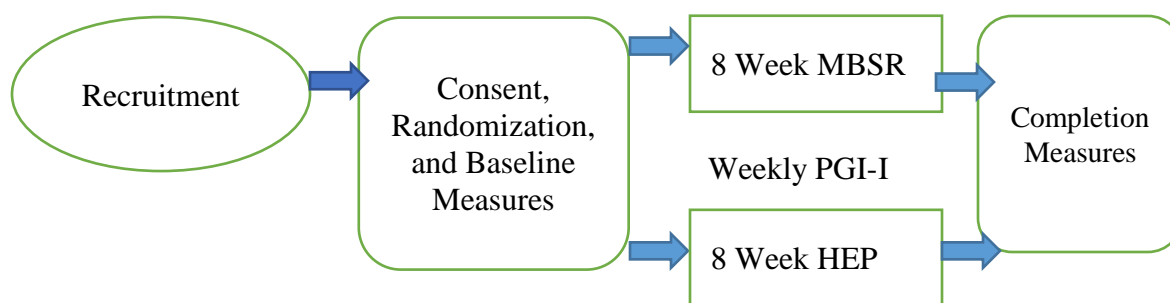


Figure 3 Design Overview

5.9 References

1. Baker J, Costa D, Guarino JM, Nygaard I. Comparison of mindfulness-based stress reduction versus yoga on urinary urge incontinence: A randomized pilot study with 6-month and 1-year follow-up visits. *Female Pelvic Med Reconstr Surg*. 2014;20(3):141-146.
2. Baker J, Costa D, Nygaard I. Mindfulness-based stress reduction for treatment of urinary urge incontinence: A pilot study. *Female Pelvic Med Reconstr Surg*. 2012;18(1):46-49.
3. Grossman P, Niemann L, Schmidt S, Walach H. Mindfulness-based stress reduction and health benefits. A meta-analysis. *J Psychosom Res*. 2004;57(1):35-43.
4. Kabat-Zinn J. Bringing mindfulness to medicine: An interview with Jon Kabat-Zinn, PhD. Interview by Carolyn Gazella. *Adv Mind Body Med*. 2005;21(2):22-27.
5. MacCoon DG, Imel ZE, Rosenkranz MA, et al. The validation of an active control intervention for mindfulness based stress reduction (MBSR). *Behav Res Ther*. 2012;50(1):3-12.
6. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. *J Psychiatr Res*. 2011;45(5):626-629.
7. McHenry JC, Insel KC, Einstein GO, Vidrine AN, Koerner KM, Morrow DG. Recruitment of older adults: Success may be in the details. *Gerontologist*. 2015;55(5):845-853.
8. Nasreddine ZS, Phillips NA, Bedirian V, et al. The Montreal Cognitive Assessment, MoCA: A brief screening tool for mild cognitive impairment. *J Am Geriatr Soc*. 2005;53(4):695-699.
9. Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: Defining standard protocol items for clinical trials. *Ann Intern Med*. 2013;158(3):200-207.
10. Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials. *BMC Med*. 2010;8:18.
11. Mohr DC, Spring B, Freedland KE, et al. The selection and design of control conditions for randomized controlled trials of psychological interventions. *Psychother Psychosom*. 2009;78(5):275-284.
12. Ospina MB, Bond K, Karkhaneh M, et al. Clinical trials of meditation practices in health care: Characteristics and quality. *J Altern Complement Med*. 2008;14(10):1199-1213.

13. Wesson J, Clemson L, Brodaty H, et al. A feasibility study and pilot randomised trial of a tailored prevention program to reduce falls in older people with mild dementia. *BMC Geriatr*. 2013;13:89.
14. Leon AC, Mallinckrodt CH, Chuang-Stein C, Archibald DG, Archer GE, Chartier K. Attrition in randomized controlled clinical trials: Methodological issues in psychopharmacology. *Biol Psychiatry*. 2006;59(11):1001-1005.
15. Nezu AM, Nezu CM. *Evidence-Based Outcome Research: A Practical Guide to Conducting Randomized Controlled Trials for Psychological Interventions*. New York: Oxford University Press; 2008.
16. Moore CG, Carter RE, Nietert PJ, Stewart PW. Recommendations for planning pilot studies in clinical and translational research. *Clin Transl Sci*. 2011;4(5):332-337.
17. Sturdy G, Hillman D, Green D, Jenkins S, Cecins N, Eastwood P. Feasibility of high-intensity, interval-based respiratory muscle training in COPD. *Chest*. 2003;123(1):142-150.
18. Sandvik H, Espuna M, Hunskaar S. Validity of the incontinence severity index: Comparison with pad-weighing tests. *Int Urogynecol J Pelvic Floor Dysfunct*. 2006;17(5):520-524.
19. Sandvik H, Seim A, Vanvik A, Hunskaar S. A severity index for epidemiological surveys of female urinary incontinence: Comparison with 48-hour pad-weighing tests. *Neurourol Urodyn*. 2000;19(2):137-145.
20. Coyne KS, Thompson CL, Lai JS, Sexton CC. An overactive bladder symptom and health-related quality of life short-form: Validation of the OAB-q SF. *Neurourol Urodyn*. 2015;34(3):255-263.
21. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav*. 1983;24(4):385-396.
22. Cohen S, Kessler, R.C., Underwood Gordon, L. *Measuring Stress: A Guide for Health and Social Scientists*. New York: Oxford University Press; 1995.
23. Cohen S, Williamson, G. Perceived stress in a probability sample of the United States. In Spacapan S, Oskamp, S. eds. *The social Psychology of Health*. Newbury Park, CA: Sage Publishers; 1988.
24. Tannenbaum C, Brouillette J, Michaud J, et al. Responsiveness and clinical utility of the geriatric self-efficacy index for urinary incontinence. *J Am Geriatr Soc*. 2009;57(3):470-475.
25. Tannenbaum C, Brouillette J, Korner-Bitensky N, et al. Creation and testing of the Geriatric Self- Efficacy Index for Urinary Incontinence. *J Am Geriatr Soc*.

2008;56(3):542-547.

26. Yalcin IB, R. Validation of two global impression questionnaires for incontinence. *Am J Obstet Gynecol*. 2003;189:98-101.
27. (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996; World Health, 2005)
28. World Health Organization. *Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation*. Geneva, Switzerland: World Health Organization; 2005.
29. IBM Corp. (2013). *IBM SPSS Statistics for Windows, Version 22.0*. Armonk, NY: IBM Corp.
30. StataCorp. (2017). *Stata Statistical Software: Release 15*. College Station, TX: StataCorp LLC.

CHAPTER 6

A FEASIBILITY RANDOMIZED CONTROLLED TRIAL: COMPARING MINDFULNESS-BASED STRESS REDUCTION WITH THE HEALTH ENHANCEMENT PROGRAM IN THE TREATMENT OF URGE URINARY INCONTINENCE IN OLDER ADULT WOMEN

Katarina Friberg Felsted, MS

Katherine Perry Supiano, PhD, LCSW, FT

Funding: This work was supported by the University of Utah College of Nursing Noorda-Hartford Fellowship, the University of Utah Office of the Associate Vice President for Health Equity and Inclusion, and the Sigma Theta Tau International Gamma Rho Chapter.

6.1 Abstract

Older adult women have the highest incidence of urge urinary incontinence in the population. Current treatment practices for this age group remain insufficient and largely ineffective. This study sought to determine the research and intervention feasibility of an RCT comparing mindfulness-based stress reduction compared with the Health Enhancement program in older adult women presenting with urge urinary incontinence.

A randomized controlled feasibility trial was developed to evaluate 3 determinants of research feasibility and three determinants of intervention feasibility.

A feasibility study examining both research and intervention feasibility determinants was conducted in a university community. Participants were recruited from the university footprint, county senior centers, and community sites.

Twenty-five postmenopausal women (mean age = 74 years) were randomized into a mindfulness-based stress reduction treatment condition or a health enhancement comparison condition for an 8-week intervention. Participants remained blinded to condition.

Research feasibility determinants were measured as recruitment, retention, and treatment fidelity; intervention feasibility determinants were measured as acceptability, tolerability, and treatment adherence.

Feasibility determinants were recorded and evaluated throughout and at completion of the study. All 6 feasibility determinants provided positive results in the enrolled population.

These positive feasibility results warrant the design of a larger scale, multisite trial to study the efficacy of mindfulness-based stress reduction in treating urge urinary

incontinence in older adult women.

6.2 Introduction

Recent studies in middle-aged women have shown that a mind-body connection may exist for persons with urge urinary incontinence (UUI)* and that the practice of mindfulness may prove helpful in relieving UUI symptoms.¹⁻³ Until now, these results have not been translated into research in the predominantly affected population: older adult women.⁴ Older adults and women continue to be underrepresented in the research literature.⁵⁻⁸

6.2.1. Background

Urinary incontinence is a pervasive, costly condition most prevalent in older adult women. It consists of two subtypes, stress urinary incontinence (SUI) and urge urinary incontinence (UUI). SUI is a structural problem, caused by weakened muscles, with straightforward and effective treatment generally available. UUI is the more common type of urinary incontinence in the older adult female population.⁹ Further, it is a more complex condition, with a variety of causes, and in many cases it is without a clear cause. The medications most often used to treat UUI carry side effects more dangerous for an older adult population: falls, dizziness, confusion, and psychosis; these side effects can threaten older adult women's independence.¹⁰ Older adult women do not currently have

* The following abbreviations are used throughout this article:

HEP: Health Enhancement Program

MBSR: Mindfulness-Based Stress Reduction

SUI: Stress Urinary Incontinence

UUI: Urge Urinary Incontinence

sufficient treatment options for UUI.

6.2.2 Purpose

The feasibility of using mindfulness-based stress reduction (MBSR) in comparison to the health enhancement program (HEP)¹¹ in treating older adult women with UUI was examined through a randomized controlled feasibility study. Feasibility determinants included both research feasibility and intervention feasibility.

6.2.3 Aims

- Aim 1: To determine the research feasibility of an RCT comparing MBSR and HEP in older adult women presenting with UUI, measured by recruitment, retention, and treatment fidelity.
- Aim 2: To determine the intervention feasibility of an RCT comparing MBSR and HEP in older adult women presenting with UUI, measured by acceptability, tolerability, and treatment adherence.

6.3 Materials and Methods

Twenty-five postmenopausal women (mean age = 74 years) experiencing at least a moderate level of UUI symptoms for at least 3 months prior to screening, were recruited into the study through a university health sciences network, a county aging services network, and community outreach. Participants were randomized into 1 of 2 conditions: the treatment condition, MBSR, and the comparison condition, HEP, for the intervention. See Section 4.12.14 for the CONSORT flowchart. Participants attended 8

weekly sessions of approximately 2 hours each with 1 half-day retreat between the 6th and 7th week. The MBSR condition was given the MBSR protocolled standardized intervention, focusing on mindfulness. The HEP condition was given the protocolled standardized intervention, focusing on functional movement, nutrition, physical activity, and music therapy. The sessions also included daily homework practice. Participants were given a modest compensation in the form of a gift card. Methods of the study were described in detail in an earlier publication.¹²

6.4 Framework

Feasibility studies are designed to assess the “potential for successful implementation and validity” of larger, subsequent intervention studies.¹³ According to Thabane and colleagues, they are practically essential to conduct.¹⁴ The researchers for this study utilized a randomized controlled trial approach resulting in the highest rigor of scientific studies. Various authors and research groups have delineated necessary protocols and best practices for feasibility studies and these were followed in this study.¹⁴⁻¹⁷ Good clinical practices, which encompass research staff training, informed consent procedures, Institutional Review Board (IRB) reporting, and monitoring/oversight procedures of both interventionists and participants were adhered to throughout.¹⁸ This feasibility study considered and implemented how best to assess safety, recruitment, ethics, and success as recommended by these researchers.^{19,20}

6.5 Results and Discussion

The feasibility results of this study are divided into research determinants and intervention determinants.

6.5.1 Research Determinants

The rationale for the selected research feasibility measures, which are defined individually below, is drawn from the recommendations of Lancaster, Leon, Thabane, Nezu & Nezu, and others.^{13-15,18,21} These researchers recommended incorporating these measures in pilot studies to evaluate the capacity of the research team to properly and successfully conduct a larger study.

6.5.1.1 Recruitment

Several results related to recruitment were discovered. A total of 143 potential participants responded to recruitment materials. Sixteen (11%) gave no further contact. As such, 127 potential participants were screened over the phone. Eighty-four of those (66%) were not eligible. Fourteen of them (11%) were not interested. Twenty-nine (23%) scheduled for enrollment. Three of the 29 cancelled before their enrollment appointment and did not reschedule. Twenty-six attended their enrollment interview. One failed the Montreal Cognitive Assessment (MoCA)²² and was declined enrollment by the researcher. The remaining 25 participants, who attended interview and passed the MoCA, provided informed consent and enrolled into the study. Recruitment percentage was 17.48%, as defined by the PI in the most conservative fashion, including those who merely responded to an email, expressing no interest. No comparison feasibility data

were shared from other MBSR studies; this is unfortunately rarely reported in the complementary medicine literature. When accounting for eligibility in recruitment calculations, the recruitment percentage was between 43.1-59.52% and serves as a more accurate range when examining feasibility. The presentation of a percentage range instead of a single percentage is due to an inability to know if the 16 who gave no further contact did so because they were ineligible or because they were not interested.

Consent rate of those who attended the enrollment interview was 100%. A consent rate of 100% is a strong indicator of feasibility. This demonstrated that the participants were well prepared for the enrollment interview meeting. Providing clear recruitment fliers, presentations, and community interactions, combined with efficient screening for eligibility and exclusions, and thoroughly reviewing the consent document together with the potential participant, allowed them to feel confident in consenting. Researchers offered each potential participant the opportunity to bring the consent document home, study it further, and discuss with family. All potential participants consented at the enrollment interview.

Researchers were able to successfully recruit from many of the recruitment sites. The sites drawing the most participants were the local county senior centers, followed by the university's Center on Aging participant registry.

6.5.1.2 Retention

Prior MBSR studies with adults of all ages have reported retention rates of 70-80%, with those studies having older participants reporting retention rates at the lower end of that range.²³⁻²⁵ Of 25 participants enrolled into the two arms of the intervention, 19

completed the intervention. This study's overall retention rate is 73.08%.

Thirteen participants were randomized into the intervention condition. One was unable to participate due to an unexpected and urgent move out of state. Another began the study with complications from cataract surgery and was hospitalized with pneumonia the second week of class. She was ill for over a month and did not return to the study. As such, 11 of the 13 enrolled and randomized into the intervention arm finished the study. This is a retention rate of 84.61%.

Twelve were randomized into the comparison condition. One dropped out before the study began, citing a withdrawal of her transportation option. Two dropped out due to volunteer and career demands (1 left on a volunteer mission; another was given additional responsibility at work and could no longer attend the daytime intervention). One deemed the intervention not helpful and stopped attending classes. Thus, 8 of the 12 in the comparison condition finished the intervention. This is a retention rate of 66.67%.

While participants remained blinded to condition throughout the study, the lower retention rate in the comparison condition is perhaps not surprising. While therapeutic in its own right, HEP remains an active control. It was created as a comparison condition to MBSR studies, matching MBSR in positive expectations, requiring an equivalent commitment from the participant and providing a plausible alternative for success.²⁶

Participants in both conditions showed mild to moderate surprise that their interventions were not treatment as usual. Unsolicited comments from at least one participant in each condition stated that they wondered if they were in the control condition, as they were not learning or practicing typical treatments for urinary incontinence. This perplexity continued for the first several weeks of class until the

participants settled into their coursework. One participant commented during week 3 “I thought I’d be doing Kegels. This is good.”

6.5.1.3 Treatment Fidelity

Determination of treatment fidelity is imperative to both external and internal validity of outcomes observed.²⁷ This study measured treatment fidelity across 5 recognized standard of science elements as suggested by Bellg and colleagues: study design, provider training, enactment of treatment skills, treatment delivery, and treatment receipt.²⁸

6.5.1.3.1 Study Design

Treatment fidelity in study design was ensured through blinding participants to condition and applying treatment doses evenly, both within and across conditions. So as to minimize confounding, the treatment and comparison conditions were held on separate days of the week and neither participants nor interventionists ever met or interacted with one another.

6.5.1.3.2 Provider Training

Treatment fidelity in provider training was established by the PI ensuring that MBSR and HEP interventionists were certified in their respective fields. Additionally, it was verified that each interventionist held appropriate and current certifications. The PI also met with the interventionists prior to the beginning of the intervention to confirm each was trained to follow their respective standardized curricula throughout the

intervention period.

6.5.1.3.3 Enactment of Treatment Skills

Treatment fidelity in enactment of treatment skills was met by substantiating that interventionists had processes in place that allowed them to “monitor and improve the ability of [participants] to perform treatment-related behavioral skills.”²⁸ These processes included monitoring and providing feedback in class practice sessions as well as providing further homework practice materials for the participants throughout the week.

6.5.1.3.4 Treatment Delivery

Treatment fidelity in treatment delivery addresses the adherence of the interventionist to the content and protocols of their curricula. This was measured from 2 perspectives, verified with both the interventionists and the participants. The PI met with each interventionist after each session to determine if the content of the intervention had been delivered. The MBSR interventionist verified content delivery at 100% across the 9 sessions. Two sessions were reported at 80%; however, that material was presented in subsequent courses. This is a per-class average of 95.55%. The HEP interventionist also confirmed 100% treatment delivery across all sessions. One session was reported at 75% and another at 90% and again the remainder of the material was delivered in subsequent sessions. This is a per-class average of 96.11% for the HEP intervention. Again, both interventionists reported overall treatment delivery of 100% across the full course.

Treatment delivery from the perspective of the participant was measured through a checklist given to the participant at the end of the intervention. Participants were asked

to mark the items that were taught throughout the course of the intervention. Each brief checklist (for both MBSR and HEP) contained 16 items and participants averaged 93% (14.9/16) using an intent-to-treat analysis. This is well above a 75% rate (12/16) which is considered as the standard of treatment delivery.¹⁵

A final feasibility measure of treatment delivery within treatment fidelity was to corroborate that each interventionist had a plan in place in case of absence. Each interventionist had 1 day that they were unable to teach and after discussion with the PI, each chose to resolve it differently. The MBSR teacher needed to be absent in Week 8, and she arranged for a trained and certified substitute. The HEP interventionist needed to be absent in Week 7, and she rescheduled the date of the course to 1 day earlier. All participants in the HEP comparison condition were willing to arrange their schedules to come at this alternate date and time. This flexibility was displayed by all participants in the condition.

6.5.1.3.5 Treatment Receipt

Treatment fidelity in treatment receipt occurred with interventionists asking questions of and discussing with the participants the content of each course. It was evaluated by having interventionists collect homework practice, logs, and charts and conferring with participants both during and after classes. In addition, interventionists made themselves available to participants between classes via email and phone.

The MBSR study condition reported 95% attendance and 96% homework practice in attendees. The HEP study condition reported 93% attendance and 93% homework practice in attendees. Absences were marked excused/unexcused; all absences in both

conditions during the study were excused, as they were due to illness, travel, hardships, or religious obligations. In most instances, the participant called before the date to let the interventionist know they would be absent and the reason for the absence. A participant who was absent would often submit their homework the week they returned. Consistent with the adult learning environment, homework was not “graded” but marked turned in/not turned in.

Each assessment of the 5 types of treatment fidelity evidenced successful outcomes.

6.5.2 Intervention Determinants

The rationale for the selected intervention feasibility measures, listed individually below, is drawn from the scientific literature regarding feasibility studies.^{21,29-32}

6.5.2.1 Acceptability

Lancaster and colleagues recommend determining acceptability in a pilot study.²¹ Acceptability in the study was measured by randomly selecting two participants after each class each week and asking them the open-ended question, “How did it go today?” This resulted in a total of 32 unstructured responses. While this is not a full representation of every participant every week, collecting that amount of information from each participant would have resulted in a participant burden that researchers deemed too high during the study design phase.

In addition to being too burdensome to participants to be asked to comment each week, researchers were concerned that this amount of feedback response could cause a

Hawthorne effect in the data. This is an unintended consequence of the participant changing their interaction as a result of the researcher's involvement.³³ In this case, the concern was that the participant might subconsciously alter their responses to elicit interviewer "approval." Thus, 2 participants were randomized and interviewed immediately after each class session.

Each of these responses was coded as positive or negative by the PI. Interrater reliability was achieved by having a second member of the research team independently code the responses as well. No discrepancies were noted between ratings and they were accepted as correct. All 32 responses were positive. This is an acceptability rate of 100% for all participants, as well as participants per condition.

This acceptability result of 100% is a strong indicator that the participants were fully accepting of an MBSR course as well as an HEP course to treat their UUI. It is postulated that this high of an acceptability percentage was influenced by hiring instructors with the highest levels of expertise and the correct certifications available. Participant comments on the MBSR instructor included, "I came and just thought the first time I did it, let it keep going going going going [sic] - it couldn't have been better - it was perfect. [Name]'s sure a great teacher - at least she sure connected with me." Participant comments on the HEP instructor included, "[Name] is always well organized - she introduces every opportunity and guides you comfortably - she is always reframing so we can all participate; I've never seen anyone not participate. She is so helpful and willing to interact personally."

The older adult women in the study often commented on the strong sense of community and pleasant group dynamics that developed in each intervention. This

appeared to be a meaningful and satisfying area for them. This is aligned with Lamb and Brady's findings that a development of community is important to older adult learners.³⁴

One woman stated after week 5, "See [Name]? She and I have lived on the same street for 3 years and never said a word to each other. And now we're friends!"

6.5.2.2 Tolerability

Tolerability was determined from number of dropouts due to stated distress from, or dislike of, either intervention experience. In this case, a greater number of such dropouts is associated with reduced tolerability. This is a separate measure from participants who need to withdraw due to a family emergency or a medical illness.^{16,32} All participants who withdrew were asked a single question, "Help me understand what made this challenging?" Of the original 25 participants, 19 completed the study. All causes for participant dropout in this study are explained in section 6.5.1.2 above, *Retention*. Only one of these dropouts was due to dislike of the intervention experience. She stated, "When it didn't seem to help I decided I wouldn't keep coming." Given these data, tolerability for the study was calculated at 96%. The only participant who dropped due to dislike was in the HEP comparison condition. Tolerability for MBSR was 100%, and tolerability for HEP was 91.67%.

6.5.2.3 Treatment Adherence

Treatment adherence was measured in two main categories at each session: attendance and homework completion. Results are reported below for those 19 participants who completed the intervention. These were tallied by the interventionist and

the PI, respectively. Attendance was recorded during all 9 sessions of the course, weeks 1 through 8 plus the retreat halfway between weeks 6 and 7. Attendance for the MBSR condition averaged 95.96% and attendance for the HEP condition averaged 97.22%.

Participants submitted each week's practice logs/homework to evidence treatment adherence. These were recorded as turned in/not turned in. Homework was recorded for 7 sessions of the course, as none was collected during week 1 or the retreat day. Homework submission for the MBSR condition averaged 88.43%. Homework submission for the HEP condition averaged 89.57%.

Participants were assured at the beginning of the intervention and throughout the course that homework participation was voluntary. The high rates of practice logs/homework indicate an eagerness by the participants to participate fully in the intervention experience and are seemingly equal across conditions.

6.6 Conclusion

The results of this study are encouraging for the development of future research studies. Recruitment, retention, treatment fidelity, acceptability, tolerability, and treatment adherence were measured and evaluated as successful. This is a wide scope to examine, and all six feasibility determinants were successfully met.

6.6.1 Limitations

This study recruited participants from one county within one state. As such, it is with caution that results are considered generalizable.

Qualitative responses were given by participants in this study, and these responses

were converted for simplicity in evaluating acceptability quantitatively for this manuscript. It is the opinion of the authors that the qualitative data will also contribute to implications and future research. Many unsolicited comments from participants were also noted and dated throughout the study and these will be considered for qualitative analysis as well. As such, a forthcoming qualitative paper will be submitted for publication upon successive qualitative analysis of these statements.

6.6.2 Implications for Future Research

The main aims of this study were to test both research and intervention feasibility determinants in the specific older adult female population with moderate to severe urge urinary incontinence. The successful feasibility results of this study help researchers prepare to design a larger scale trial. Increases in the older adult population and the cost of treating UUI makes this research all the timelier and are factors that spur future research. A multisite trial examining efficacy of treatment can now be designed, as concerns regarding feasibility in this specific population are alleviated.

Older adult women deserve better options for treating this condition. These findings point to the need for future research to determine whether mindfulness-based stress reduction can provide this needed treatment.

6.6.3 Acknowledgements

The researchers gratefully acknowledge the study's funding sources. The study sponsors had no involvement in the study design, collection, analysis, data interpretation, writing of the manuscript, or the decision to submit for publication.

The researchers also gratefully acknowledge the guidance from the following faculty at the University of Utah: Dr. Michael Caserta, Dr. Angela Deneris, Dr. Jia-Wen Guo, and Dr. Paul Thielking.

6.7 References

1. Griffiths D, Tadic SD. Bladder control, urgency, and urge incontinence: Evidence from functional brain imaging. *Neurourol Urodyn*. 2008;27(6):466-474.
2. Baker J, Costa D, Guarino JM, Nygaard I. Comparison of mindfulness-based stress reduction versus yoga on urinary urge incontinence: A randomized pilot study with 6-month and 1-year follow-up visits. *Female Pelvic Med Reconstr Surg*. 2014;20(3):141-146.
3. Baker J, Costa D, Nygaard I. Mindfulness-based stress reduction for treatment of urinary urge incontinence: A pilot study. *Female Pelvic Med Reconstr Surg*. 2012;18(1):46-49.
4. Markland AD, Richter HE, Fwu CW, Eggers P, Kusek JW. Prevalence and trends of urinary incontinence in adults in the United States, 2001 to 2008. *J Urol*. 2011;186(2):589-593.
5. Devlin G. Women and elderly: Subgroups under-represented in clinical trials. *Curr Opin Cardiol*. 2010;25(4):335-339.
6. Provencher V, Mortenson WB, Tanguay-Garneau L, Belanger K, Dagenais M. Challenges and strategies pertaining to recruitment and retention of frail elderly in research studies: A systematic review. *Arch Gerontol Geriatr*. 2014;59(1):18-24.
7. Barriers to women's participation in clinical trials and SWHR proposed solutions. <https://swhr.org/barriers-to-womens-participation-in-clinical-trials-and-sw-hr-proposed-solutions/>. Accessed November 14, 2017.
8. Mody L, Miller DK, McGloin JM, et al. Recruitment and retention of older adults in aging research. *J Am Geriatr Soc*. 2008;56(12):2340-2348.
9. Buckley BS, Lapitan MC, Epidemiology Committee of the Fourth International Consultation on Incontinence. Prevalence of urinary incontinence in men, women, and children--current evidence: Findings of the Fourth International Consultation on Incontinence. *Urology*. 2010;76(2):265-270.
10. Franco I. The central nervous system and its role in bowel and bladder control. *Current Urology Reports*. 2011;12(2):153-157.
11. MacCoon DG, Imel ZE, Rosenkranz MA, et al. The validation of an active control intervention for mindfulness based stress reduction (MBSR). *Behav Res Ther*. 2012;50(1):3-12.
12. Felsted KS, Supiano KP, Guo JW. Designing rigorous methods in integrative research: comparing mindfulness-based stress reduction with the health enhancement program in the treatment of urge urinary incontinence in older adult women: A pilot feasibility and randomized controlled trial. (in progress)

13. Tickle-Degnen L. Nuts and bolts of conducting feasibility studies. *Am J Occup Ther.* 2013;67(2):171-176.
14. Thabane L, Ma J, Chu R, et al. A tutorial on pilot studies: The what, why and how. *BMC Med Res Methodol.* 2010;10:1.
15. Nezu AM, Nezu CM. *Evidence-Based Outcome Research: A Practical Guide to Conducting Randomized Controlled Trials for Psychological Interventions.* New York: Oxford University Press; 2008.
16. Moore CG, Carter RE, Nietert PJ, Stewart PW. Recommendations for planning pilot studies in clinical and translational research. *Clin Transl Sci.* 2011;4(5):332-337.
17. Whitehead AL, Sully BG, Campbell MJ. Pilot and feasibility studies: Is there a difference from each other and from a randomised controlled trial? *Contemp Clin Trials.* 2014;38(1):130-133.
18. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. *J Psychiatr Res.* 2011;45(5):626-629.
19. World Health Organization. *Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation.* Geneva, Switzerland: World Health Organization; 2005.
20. Center for Drug E, Research, Center for Biologics E, Research, International Conference on H. Guidance for industry : E6 good clinical practice, consolidated guidance. 2000.
21. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: Recommendations for good practice. *J Eval Clin Pract.* 2004;10(2):307-312.
22. Nasreddine ZS, Phillips NA, Bedirian V, et al. The Montreal Cognitive Assessment, MoCA: A brief screening tool for mild cognitive impairment. *J Am Geriatr Soc.* 2005;53(4):695-699.
23. Gallegos AM, Hoerger M, Talbot NL, et al. Toward identifying the effects of the specific components of mindfulness-based stress reduction on biologic and emotional outcomes among older adults. *J Alt Complement Med.* 2013;19(10):787-792.
24. White KS, Allen LB, Barlow DH, Gorman JM, Shear MK, Woods SW. Attrition in a multicenter clinical trial for panic disorder. *J Nerv Ment Dis.* 2010;198(9):665-671.
25. Creswell JD, Irwin MR, Burklund LJ, et al. Mindfulness-based stress reduction training reduces loneliness and pro-inflammatory gene expression in older adults: A small randomized controlled trial. *Brain Behav Immun.* 2012;26(7):1095-1101.

26. Kok BE, Waugh, Christian E., Fredrickson, Barbara L. Meditation and health: The search for mechanisms of action. *Soc Personal Psychol Compass*. 2013;7(1):27-39.
27. Hildebrand MW, Host HH, Binder EF, et al. Measuring treatment fidelity in a rehabilitation intervention study. *Am J Phys Med Rehabil*. 2012;91(8):715-724.
28. Bellg AJ, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol*. 2004;23(5):443-451.
29. Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Med Res Methodol*. 2010;10:67.
30. Bowen DJ, Kreuter M, Spring B, et al. How we design feasibility studies. *Am J Prev Med*. 2009;36(5):452-457.
31. Morin KH. Value of a pilot study. *J Nurs Educ*. 2013;52(10):547-548.
32. Sturdy G, Hillman D, Green D, Jenkins S, Cecins N, Eastwood P. Feasibility of high-intensity, interval-based respiratory muscle training in COPD. *Chest*. 2003;123(1):142-150.
33. Holden JD. Hawthorne effects and research into professional practice. *J Eval Clin Pract*. 2001;7(1):65-70.
34. Lamb R, Brady EM. Participation in lifelong learning institutes: What turns members on? *Educational Gerontology*. 2005;31:207-224.

CHAPTER 7

RESULTS

The results of the two primary feasibility analyses were addressed in the prior feasibility results article. The results of the final, exploratory aim for this trial are addressed in this chapter.

- **Exploratory aim:** To evaluate the short-term preliminary efficacy of MBSR for treatment of UI in older adult women, in comparison to HEP, including symptom severity, symptom bother, perceived stress, perceived self-efficacy, and the rate and trajectory of change.

The preliminary efficacy measures included both outcome and process measures for each treatment condition, as outlined in Section 7.6.1, Table 6. Four outcome measures (Incontinence Severity Index, Overactive Bladder Questionnaire Short Form, Perceived Stress Scale, and Geriatric Self Efficacy—Urinary Incontinence) were collected at enrollment and administered again at completion of the intervention, to evaluate severity, bother, perceived stress, and perceived self-efficacy, respectively. Additionally, one process measure (Patient Global Impression of Improvement) was administered after each class session, for a total of nine times, to evaluate the trajectory and rate of change.

All data were analyzed using intent-to-treat analysis (ITT). This protocol entails all data being incorporated when calculating findings, including data from those who discontinued the study ($n = 6$, 24%). This serves as a basic solution to noncompletion and missing outcomes in randomized controlled trials (Gupta, 2011). In this study, all participants who withdrew from the study (with the exception of one participant who suddenly needed to move from the state), returned to complete the outcome and process measures at study completion ($n = 5$, 20%). As such, all data analysis is calculated with

all data available, including the data from those participants who withdrew. While this produces more conservative results, it is best practice to account for overall efficacy in a randomized controlled trial, as it acknowledges that clinical practice would encounter deviations from protocol as well as noncompletion (Heritier, Gebski, & Keech, 2003).

7.1 Demographics

Demographic measures were collected at enrollment. The demographic variables were divided into continuous and categorical values and frequency statistics were calculated (7.6.2, Tables 7 and 8). These were compared between treatment conditions to determine whether or not participants in each treatment condition were statistically similar to one another (7.6.3, Tables 9 and 10). Values such as age, BMI, length of UUI, number of deliveries, and age of menopause onset did not show significant differences. Specifics regarding these and other values, including range and means, are explained in detail below.

7.1.1 Comparison of Mean Ranks

No significant differences were observed in the mean ranks between the MBSR and HEP conditions at $p < .05$.

7.1.1.1 Age

The mean of the ranks for the MBSR condition was 12.85, while the mean of the ranks of the HEP condition was 13.17 ($U = 76.00$, $p = .91$). The mean age in the MBSR condition was 73.92 ($SD = 7.22$) with a range of 66-87, while the mean age in the HEP

condition was 73.08 ($SD = 9.93$) with a range of 56-87). There were no significant differences at $p < .05$.

7.1.1.2 BMI

The mean of the ranks for the MBSR condition was 11.00, while the mean of the ranks of the HEP condition was 15.17 ($U = 52.00$, $p = .16$). The mean BMI in the MBSR condition was 25.58 ($SD = 4.57$), with a range of 18.37 – 32.53, while the mean BMI in the HEP condition was 31.31 ($SD = 11.43$) with a range of 20.32 - 61.08. There were no significant differences at $p < .05$.

7.1.1.3 Number of Deliveries

The mean of the ranks for the MBSR condition was 12.42, while the mean of the ranks of the HEP condition was 13.63 ($U = 70.50$, $p = .68$). The mean number of deliveries in the MBSR condition was 3.46 ($SD = 3.05$) with a range of 0 - 12, while the mean number of deliveries in the HEP condition was 3.42 ($SD = 2.02$) with a range of 0-6. There were no significant differences at $p < .05$.

7.1.1.4 Age of Onset of Menopause

The mean of the ranks for the MBSR condition was 12.50, while the mean of the ranks of the HEP condition was 9.00 ($U = 36.00$, $p = .20$). The mean age of onset of menopause in the MBSR condition was 54.42 ($SD = 7.79$) with a range of 40 - 60, while the mean age of onset of menopause in the HEP condition was 48.33 ($SD = 4.00$) with a range of 44 - 56. There were no significant differences at $p < .05$.

7.1.1.5 Length of Urge Incontinence (Years)

The mean of the ranks for the MBSR condition was 12.85, while the mean of the ranks of the HEP condition was 13.17 ($U = 76.00$, $p = .91$). The mean number of years with urge incontinence in the MBSR condition was 9.56 ($SD = 13.16$) with a range of 4 months to 50 years, while the mean number of years with urge incontinence in the HEP condition was 6.25 ($SD = 3.84$) with a range of 1 – 13 years. There were no significant differences at $p < .05$.

7.1.1.6 Number of Prescription Medications

The mean of the ranks for the MBSR condition was 10.23, while the mean of the ranks of the HEP condition was 12.77 ($U = 46.50$, $p = .35$). The mean number of prescription medications used in the MBSR condition was 3.09 ($SD = 2.26$) with a range of 1 – 8, while the mean number of prescription medications in the HEP condition was 3.64 ($SD = 1.80$) with a range of 1 - 7. There were no significant differences at $p < .05$.

7.1.1.7 Daily Caffeine Use (Servings)

The mean of the ranks for the MBSR condition was 11.96, while the mean of the ranks of the HEP condition was 13.04 ($U = 65.50$, $p = .70$). The MBSR condition reported consuming a mean of 1.17 ($SD = 1.27$) servings of caffeine daily with a range of 0 - 4, while the HEP condition reported 1.50 ($SD = 1.62$) servings of caffeine daily with a range of 0 - 4. There were no significant differences at $p < .05$.

7.1.1.8 Types of Physical Health Conditions Reported

The mean of the ranks for the MBSR condition was 10.85, while the mean of the ranks of the HEP condition was 13.50 ($U = 50.00$, $p = .29$). The MBSR condition reported a mean of .38 ($SD = .65$) of the 4 types of physical health conditions (high blood pressure, diabetes, cancer, heart problems), while the HEP condition reported a mean of .90 ($SD = 1.20$) of the health conditions. There were no significant differences at $p < .05$.

7.1.1.9 Types of Mental Health Conditions Reported

The mean of the ranks for the MBSR condition was 11.88, while the mean of the ranks of the HEP condition was 12.15 ($U = 63.50$, $p = .85$). The MBSR condition reported a mean of .08 ($SD = .28$) of the 2 types of mental health conditions (anxiety, depression), while the HEP condition reported a mean of .10 ($SD = .32$) of the mental health conditions. There were no significant differences at $p < .05$.

7.1.1.10 Types of Prescription Medications Reported

The mean of the ranks for the MBSR condition was 13.19, while the mean of the ranks of the HEP condition was 12.79 ($U = 75.50$, $p = .88$). The MBSR condition reported a mean usage of .62 ($SD = .65$) of the 4 types of prescription medications (antidepressants/anxiolytics, sleep medications, pain medications, beta-blockers), while the HEP condition reported a mean of .58 ($SD = .67$) of the types of prescription medications used. There were no significant differences at $p < .05$.

7.2 Outcome Measures

7.2.1 Reliability

Statistical analysis on outcome measures began with reliability calculations of each scale. The Cronbach's α score was calculated for each outcome measure. Cronbach's α values are accepted as 0.5 - <0.6 poor, 0.6 - <0.7 questionable, .0.7 - <0.8 acceptable, 0.8 - <.09 good, and ≥ 0.90 excellent (Cronbach, 1951; Taber, 2016). The Incontinence Severity Index showed below poor reliability in this sample, with a Cronbach's $\alpha = 0.46$. The ISI contains two questions. The length of the test affects the α value: According to several authors, if the length of the test is too short, the α value is reduced (Streiner, 2003; Tavakol & Dennick, 2011). Additionally, as this was mainly a feasibility study, the sample size is quite small which can also affect the α value (Button et al., 2013).

The Overactive Bladder Questionnaire (OAB-q) contains 19 questions, with $\alpha = .88$ in this sample. As explained in Chapter 4, while the scale is only validated as a whole to measure bother, it contains two parts, the first measuring severity and the second measuring bother (Pfizer representative Sheryl, personal communication, August 26, 2016). As such, Cronbach's α values for part 1 and part 2 of the OAB-q were also calculated, with Cronbach's α scores equaling $\alpha = .70$ and $\alpha = .87$, respectively. The overall and the Part 2 reliability coefficients are interpreted as strong, while the Part 1 coefficient is interpreted as moderate.

The Perceived Stress Scale (PSS) has 10 items and an $\alpha = .85$ in this sample, indicating strong reliability. The Geriatric Self-Efficacy Urinary Incontinence Scale Cronbach's α remained the same value, $\alpha = .91$, testing with the original 12 questions and

with the added adapted question totaling 13 questions, both indicating strong reliability. Additionally, the same α score in the original GSE-UI (12 questions) and the adapted GSE-UI (13 questions) indicates that the added question does not provide a stronger reliability with its inclusion.

7.2.2 Assumptions of Normality

Prior to analyzing each test, assumptions of normality were examined (see Chapter 4). The Kolmogorov-Smirnov test was prioritized over the Shapiro-Wilk test for evaluating assumptions of normality, as the Shapiro-Wilk is the stricter of the tests and a less appropriate fit for a small feasibility study. Additional ways of testing normality assumptions were analyzed for each data set, including the Fisher's skewness coefficient, the kurtosis coefficient, the histogram, and the Q-Q plot. These are presented in Section 7.6.5. While there is some conflict in normality outcomes, the majority of tests support normality.

7.3 Key Findings

7.3.1 Overall Intervention Results

All outcome measures were administered before and after the intervention in both treatment conditions. Data were analyzed to uncover whether participants saw improvement. Participants saw significant improvement in all four outcome measures: Severity, bother, perceived stress, and perceived self-efficacy. A paired t test was conducted to compare the overall pre- and postdifferences for ISI scores. There was a significant decrease in ISI scores at posttest ($M = 5.08$, $SD = 3.5$) compared to pretest (M

= 8.00, $SD = 3.02$; $t = 4.32$, $df = 23$, $p = .00$). A paired t test to compare pre- and post-OAB-q scores showed a similar decrease in OAB-q scores from pre- ($M = 66.79$, $SD = 17.84$) to posttest ($M = 44.88$, $SD = 19.59$, $t = 5.55$, $df = 23$, $p = .00$). Paired t tests also showed a significant decrease in PSS scores at posttest ($M = 9.79$, $SD = 8.09$) compared with pretest PSS scores ($M = 12.29$, $SD = 7.07$, $t = 2.34$, $p = .01$), and a significant increase in GSE-UI scores (pretest: $M = 65.83$, $SD = 28.84$; posttest: $M = 77.13$, $SD = 35.16$, $t = -2.26$, $df = 23$, $p = .02$).

The nonparametric test, Wilcoxon Signed-Ranks, was also conducted to determine if the pre- and posttest scores for the Likert scale ISI, OAB-q, PSS, and GSE-UI questions showed participant improvement. The medians for the pretest and posttest ISI scores were 8.00 and 4.00, respectively. We found a significant effect for ISI in favor of lower posttest scores (the mean ranks for positive and negative ranks were 5.50 and 10.00 respectively; $Z = -3.27$, $p = .00$). The medians for the pretest and posttest OAB-q scores were 65.00 and 40.50, respectively. There was a significant effect for OAB-q (the mean ranks for the positive and negative ranks were 7.50 and 12.20, respectively; $Z = -3.97$, $p = .00$). Similarly, there was a significant effect for PSS in favor of lower PSS scores at posttest; the mean rank for negative ranks was 15.73 and 7.15 for positive ranks, $Z = -2.03$, $p = .02$. The median pretest score for PSS was 13.00 and the median posttest score was 7.50. There was a significant effect for GSE-UI in favor of higher posttest GSE-UI scores than pretest scores. The median pretest GSE-UI score was 67.00 and the median posttest score was 79.00. The mean rank for the negative ranks was 10.06 while the mean rank for the positive ranks were 13.72, $Z = -1.99$, $p = <.05$. These significant changes are reported in Section 7.6.5, Table 12.

7.3.2 Within-Condition Results

I also examined if significant within-condition improvement occurred (i.e., if the participants in the MBSR condition and/or the HEP significantly improved on outcome measures from enrollment to completion). Within- condition comparisons were analyzed with paired samples t tests and their nonparametric version, the Wilcoxon signed rank test.

Paired t tests were conducted to evaluate whether the pre- and postscores showed improvement in the MBSR and HEP groups, respectively.

In the MBSR group, there was a significant decrease in ISI scores at posttest ($M = 4.08$, $SD = 3.45$) compared to pretest ($M = 7.00$, $SD = 3.19$; $t = 2.80$, $df = 11$, $p = .01$). A paired t test to compare pre- and post-OAB-q scores showed a similar decrease in OAB-q scores from pre- ($M = 64.25$, $SD = 21.16$) to posttest ($M = 38.83$, $SD = 17.73$, $t = 5.12$, $df = 11$, $p = .00$). Paired t tests also showed a significant decrease in PSS scores at posttest ($M = 7.92$, $SD = 7.29$) compared with pretest PSS scores ($M = 11.00$, $SD = 8.74$, $t = 1.96$, $p = .04$), and a significant increase in GSE-UI scores (pretest: $M = 71.83$, $SD = 34.09$; posttest: $M = 88.33$, $SD = 36.37$, $t = -2.60$, $df = 11$, $p = .01$).

In the HEP group, there was a significant decrease in ISI scores at posttest ($M = 6.08$, $SD = 3.45$) compared to pretest ($M = 9.00$, $SD = 2.59$; $t = 3.21$, $df = 11$, $p = .00$). A paired t test to compare pre- and post-OAB-q scores showed a similar decrease in OAB-q scores from pre- ($M = 69.33$, $SD = 14.27$) to posttest ($M = 50.92$, $SD = 20.21$, $t = 2.93$, $df = 11$, $p = .01$). Paired t tests did not show a significant decrease in PSS scores at posttest ($M = 11.67$, $SD = 8.72$) compared with pretest PSS scores ($M = 13.58$, $SD = 7.49$, $t = 1.28$, $p = .11$). The increase in GSE-UI scores (pretest: $M = 59.83$, $SD = 22.33$; posttest:

$M = 65.92$, $SD = 31.43$, $t = -.793$, $df = 11$, $p = .22$) did not reach significance.

The nonparametric test, Wilcoxon Signed-Ranks, was also conducted to examine if the pre- and posttest scores for the Likert-type scale ISI, OAB-q, PSS, and GSE-UI questions showed participant improvement.

In the MBSR group, the medians for the pretest and posttest ISI scores were 6.00 and 2.50, respectively. We found a significant effect for ISI in favor of lower posttest scores (the mean ranks for positive and negative ranks were 4.00 and 5.13, respectively; $Z = -2.23$, $p = .01$). The medians for the pretest and posttest OAB-q scores were 64.00 and 34.50, respectively. There was a significant effect for OAB-q (the mean ranks for the positive and negative ranks were .00 and 6.50, respectively; $Z = -3.06$, $p = .00$). There was no significant effect for PSS in favor of lower PSS scores at posttest; the mean rank for negative ranks was 9.00 and 3.50 for positive ranks, $Z = -1.08$, $p = .14$. The median pretest score for PSS was 13.00 and the median posttest score was 5.50. There was a significant effect for GSE-UI in favor of higher posttest GSE-UI scores than pretest scores. The median pretest GSE-UI score was 84.00 and the median posttest score was 102.50. The mean rank for the negative ranks was 9.00 while the mean rank for the positive ranks were 6.27, $Z = -2.35$, $p = <.05$.

In the HEP group, the medians for the pretest and posttest ISI scores were 8.50 and 7.00, respectively. We found a significant effect for ISI in favor of lower posttest scores (the mean ranks for positive and negative ranks were 2.00 and 5.38, respectively; $Z = -2.44$, $p = .01$). The medians for the pretest and posttest OAB-q scores were 66.50 and 47.50, respectively. There was a significant effect for OAB-q (the mean ranks for the positive and negative ranks were 4.00 and 6.20, respectively; $Z = -2.58$, $p = .01$). There

was no significant effect for PSS in favor of lower PSS scores at posttest; the mean rank for negative ranks was 7.13 and 5.25 for positive ranks, $Z = -1.42$, $p = .08$. The median pretest score for PSS was 11.00 and the median posttest score was 9.50. There was no significant effect for GSE-UI in favor of higher posttest GSE-UI scores than pretest scores. The median pretest GSE-UI score was 61.00 and the median posttest score was 63.00. The mean rank for the negative ranks was 4.64 while the mean rank for the positive ranks were 9.10, $Z = -.51$, $p = .31$.

The paired t tests and the Wilcoxon signed ranks test produced statistically similar results, with the exception of the MBSR PSS results (Section 7.6.6 Tables 13, 14).

7.3.3 Between-Condition Results

Each outcome measure corresponds to one of four research questions related to the exploratory aim. All research questions were analyzed using both independent t tests and their nonparametric equivalent, Mann Whitney U tests. These results are summarized in Section 7.6.8, Tables 15, 16. These results were obtained using intent-to-treat analysis. Below is a between-condition comparison of the conditions congruent with the research questions.

7.3.3.1 RQ 1 Does MBSR Reduce UI Severity in Older Adult Women as Compared to HEP?

Severity was analyzed by the Incontinence Severity Index (ISI) and informally through the OAB-q SF Part 1 scores. Independent samples t tests and Mann Whitney U tests were conducted to examine if MBSR reduced UI severity in older adult women

compared to HEP for these Likert-type scale questions. The mean scores for participants in the MBSR condition and the HEP condition at posttest were 4.08 ($SD = 3.45$) and 6.08 ($SD = 3.45$), respectively. The independent samples t test indicated that there were no significant differences in posttest ISI scores ($t = -1.42$, $df = 22$, $p = .07$). The Mann-Whitney U test confirmed the nonsignificant finding (the mean rank for the MBSR condition was 10.38, while the mean rank for the HEP condition was 14.63; $U = 46.50$, $Z = -1.49$, $p = .07$). No differences were found between groups when measuring severity with the ISI.

Means for the OAB-q Part 1 scores among participants in the MBSR and HEP condition were 23.00 ($SD = 11.46$) and 30.92 ($SD = 14.99$), respectively. While no significant differences in OAB-q part 1 scores were found between groups with the independent samples t test ($t = -1.45$, $df = 22$, $p = .08$), the Mann-Whitney U test results showed statistical significance (the mean rank for the MBSR condition was 9.71, while the mean rank for the HEP condition was 15.29; $U = 38.50$, $Z = -1.94$, $p = .03$). The nonparametric test showed differences between conditions.

7.3.3.2 RQ 2: Does MBSR Reduce UUI *Bother* in Older Adult Women

as Compared to HEP?

Bother was analyzed by the overall and Part 2 (HRQL) scores of the OAB-q SF. Independent samples t tests and Mann Whitney U tests were conducted to evaluate the difference between conditions at posttest for these Likert-type scale questions. Mean scores for the overall OAB-q scores were 38.83 ($SD = 17.73$) and 50.92 ($SD = 20.21$) for the MBSR and HEP conditions, respectively. The independent samples t test found that

the differences between conditions was not significant ($t = -1.56$, $df = 22$, $p = .07$) at posttest. The Mann-Whitney U test showed significant differences between groups at posttest (the mean rank for the MBSR condition was 9.75, while the mean rank for the HEP condition was 15.25; $U = 39.00$, $Z = -1.91$, $p = .03$). The parametric test showed no differences while the nonparametric tests showed a difference.

Similarly, OAB-q Part 2 scores which measure bother specifically, were lower in the MBSR condition ($M = 23.00$, $SD = 11.46$) compared to HEP ($M = 30.92$, $SD = 14.99$) at posttest. The results of the independent samples t test indicated that differences in OAB-q Part 2 scores were not significant ($t = -1.45$, $df = 22$, $p = .08$), although the results from the Mann-Whitney U test showed statistical significance (the mean rank for the MBSR condition was 9.71, while the mean rank for the HEP condition was 15.29; $U = 38.50$, $Z = -1.94$, $p = .03$). Again, the parametric test showed no differences while the nonparametric tests showed a difference.

7.3.3.3 RQ 3: Does MBSR Reduce Older Adult Women's Perceived Stress in Older Adult Women as Compared to HEP?

Perceived stress was analyzed by the Perceived Stress Scale (PSS) scores. While PSS means were lower for participants in the MBSR condition ($M = 7.92$, $SD = 7.29$) compared to participants in the HEP condition ($M = 11.67$, $SD = 8.72$) at posttest, no significant difference was found between the MBSR and HEP conditions using an independent samples t test ($t = -1.14$, $df = 22$, $p = .14$) and Mann-Whitney U test (the mean rank for the MBSR condition was 10.63, while the mean rank for the HEP condition was 14.38; $U = 49.50$, $Z = -1.30$, $p = .10$). This indicates that there was no

difference between groups when measuring perceived stress.

7.3.3.4 RQ 4: Does MBSR Increase Older Adult Women's *Self-Efficacy*

Surrounding Self-Management of UUI Symptoms as Compared to HEP?

Perceived self-efficacy was analyzed by the adapted Geriatric Self-Efficacy Index for Urinary Incontinence (GSE-UI). While mean scores were higher for participants in the MBSR condition ($M = 88.33$, $SD = 36.37$) compared to the HEP condition ($M = 65.92$, $SD = 31.43$), an independent samples t test and Mann-Whitney U test were conducted to assess if these differences were significant. The t test found no significant differences between conditions at posttest for GSE-UI, $t = 1.62$, $df = 22$, $p = .06$. The Mann-Whitney U test found no significant differences at posttest as well (the mean rank for the MBSR condition was 14.75, while the mean rank for the HEP condition was 10.25; $U = 45.00$, $Z = -1.56$, $p = .06$). This indicates that there was no difference between groups when measuring perceived self-efficacy.

7.3.4 Process Measure

7.3.4.1 RQ 5: What is the *Rate and Trajectory of Change*, as Reported by

Participants in Each Condition?

The process measure, used to evaluate rate and trajectory of change in the study, is the Patient Global Impression of Improvement (PGI-I). It is difficult to psychometrically evaluate a single Likert-type item, such as the PGI-I, as conventional reliability methods (e.g., Cronbach's alpha) are not applicable (Gliem & Gliem, 2003); however, the measure is ubiquitously used and has demonstrated desirable validity and

reliability characteristics (Marshall, 2007).

The PGI-I data were analyzed using a linear mixed effects model. For this modeling, the SPSS data were converted into Excel files and exported into STATA. Three models were explored. Model 1 evaluated the overall data from the entire sample size without considering differences by randomized treatment (e.g., MBSR versus HEP). This model showed statistically significant increase in PGI-I across the weeks of the intervention ($b = 0.17$; $p < 0.001$). Model 2 is the preferred model of the three considered and specifies the effect of randomized treatment, which shows a statistically significant positive effect for the MBSR condition versus the HEP condition ($b = 0.48$; $p < 0.05$). In Model 2, the time trajectory remains highly significant ($b = 0.17$; $p < 0.001$), as in Model 1. Model 3 specifies an interaction between time and experimental condition, as well as main effect for these two terms. In Model 3, the coefficients show non-statistically significant effect of the time*treatment interaction term. While the interaction was statistically nonsignificant, it was in the predicted direction, suggesting a nominally higher slope for the MBSR condition. It is worth noting that the model is weakly powered to detect interaction effects (Yalcin & Bump, 2003), thus larger sample sizes will be necessary to follow up on the suggestive interaction result. Finally, including the interaction effect fails to improve model fit as assessed by likelihood ratio test ($\chi^2 = 1.39$; $p > 0.05$); thus, Model 2 is the preferred model (Section 7.6.7). This indicates that there were differences between the MBSR condition and the HEP condition.

7.3.5 Effect Size and Power Analysis

While researchers often only report p values to indicate statistical significance, this can be a limitation. Further, effect sizes are typically not reported unless the p values are significant. P values depend to some degree on standard error; a larger sample size decreases standard error and lowers the p value (Altman & Bland, 2005). In fact, a statistically significant p value, according to Tomczak and Tomczak, sometimes “mainly indicates that a huge sample size was used” (2014, p. 20; Bradley & Brand, 2013; Sullivan & Feinn, 2012). P values as such do not indicate the strength of the relationship between the variables (Fritz, Morris, & Richler, 2012). Thus, Tomczak and Tomczak (2014) recommend reporting the effect size estimates alongside null findings.

Effect sizes were calculated for between-condition results from the independent samples t tests, and were reported as Cohen’s d . Cohen’s d scores are accepted as 0.2 = weak, 0.5 = moderate, and 0.8 indicating strong reliability (Ellis, 2010). Three of the four outcome measures (ISI, OAB-q, and GSE-UI) were found to have moderate effect sizes (ISI ES = .58, power = 27%; OAB-q ES = .64, power = 32%; GSE-UI ES = .66, power = 34%; Table 15). The fourth, PSS, was found to have low effect size, PSS ES = .47, power = 20%. Since this is a pilot study, we also examined post-hoc power analyses. Power analyses were calculated and were low, as expected, due to a small sample size (Section 7.6.8 Table 15 and 16).

Effect sizes were also calculated for results from the Mann-Whitney U tests and r coefficients were reported. ISI, PSS, and GSE-UI showed weak effects while OAB-q showed a strong effect (ISI ES = .32, OAB-q ES = .73, PSS ES = .34, GSE-UI ES = .31). Effect sizes for the Mann-Whitney U tests are reported in Table 16.

7.3.6 Follow-Up Wave

The data collection from the follow-up wave of this randomized controlled trial, conducted during November and December of 2017, will be analyzed in January 2018. These data are outside the scope of the dissertation. The data from this additional wave, examining whether improvement in each condition was sustained, may strengthen the analysis of dissertation findings reported here.

7.4 Acknowledgments

The author gratefully acknowledges Dr. Kathie Supiano for her leadership and Dr. Jia-Wen Guo, Dr. Daniel Adkins, Yeonjung Jo, and Djin Lai for their generous statistical guidance.

7.5 References

- Altman, D. G., & Bland, J. M. (2005). Standard deviations and standard errors. *BMJ*, 331(7521), 903. doi:10.1136/bmj.331.7521.903
- Bradley, M. T., & Brand, A. (2013). Alpha values as a function of sample size, effect size, and power: accuracy over inference. *Psychology Report*, 112(3), 835-844. doi:10.2466/03.49.PR0.112.3.835-844
- Button, K. S., Ioannidis, J. P., Mokrysz, C., Nosek, B. A., Flint, J., Robinson, E. S., & Munafò, M. R. (2013). Power failure: Why small sample size undermines the reliability of neuroscience. *Nature Reviews Neuroscience*, 14(5), 365-376. doi:10.1038/nrn3475
- Cronbach, L. J. (1951). Coefficient alpha and the internal structure of tests. *Psychometrika*, 16(3), 297-334.
- Ellis, P. D. (2010). *The essential guide to effect sizes* (1st ed.). Cambridge, UK: Cambridge University Press.
- Fritz, C. O., Morris, P. E., & Richler, J. J. (2012). Effect size estimates: Current use, calculations, and interpretation. *Journal of Experimental Psychology: General*, 141(1), 2-18. doi:10.1037/a0024338
- Gliem, J. A., & Gliem, R. R. (2003). *Calculating, interpreting, and reporting Cronbach's alpha reliability coefficient for Likert-type scales*. Paper presented at the ScholarWorks 2003 Conference, Ohio State University, Columbus, Ohio.
- Gupta, S. K. (2011). Intention-to-treat concept: A review. *Perspectives in Clinical Research*, 2(3), 109-112. doi:10.4103/2229-3485.83221
- Heritier, S. R., Gebski, V. J., & Keech, A. C. (2003). Inclusion of patients in clinical trial analysis: The intention-to-treat principle. *Medical Journal of Australia*, 179(8), 438-440.
- Marshall, S. W. (2007). Power for tests of interaction: Effect of raising the Type 1 error rate. *Epidemiologic Perspectives & Innovations*, 4(4), 1-7.
- Streiner, D. L. (2003). Starting at the beginning: an introduction to coefficient alpha and internal consistency. *Journal of Personality Assessment*, 80(1), 99-103. doi:10.1207/S15327752JPA8001_18
- Sullivan, G. M., & Feinn, R. (2012). Using effect size-or why the *p* value is not enough. *Journal of Graduate Medical Education*, 4(3), 279-282. doi:10.4300/JGME-D-12-00156.1
- Taber, K. S. (2017). The use of Cronbach's alpha when developing and reporting research instruments in science education. *Research and Science Education*, 1-24.

doi:10.1007/s11165-016-9602-2..

- Tavakol, M., & Dennick, R. (2011). Making sense of Cronbach's alpha. *International Journal of Medical Education*, 2, 53-55. doi:10.5116/ijme.4dfb.8dfd
- Tomczak, M., & Tomczak, E. (2014). The need to report effect size estimates revisited. An overview of some recommended measures of effect size. *TRENDS in Sport Sciences*, 1(21), 19-25.
- Yalcin, I., & Bump, R. (2003). Validation of two global impression questionnaires for incontinence. *American Journal of Obstetrics and Gynecology*, 189, 98-101.

7.6 Supplementary Information

7.6.1 Outcome and Process Measures

Table 6 Outcome and Process Measures

Preliminary Efficacy	<i>Instrument</i>	<i>Administered</i>
Symptom Severity (<i>Outcome Measure</i>)	Incontinence Severity Index Part 1 of Overactive Bladder Questionnaire Short Form (Q1-6)	At baseline and at study completion, by participant
Symptom Bother (<i>Outcome Measure</i>)	Overactive Bladder Questionnaire Short Form Overall and Part 2 (HRQL) specifically	At baseline and at study completion, by participant
Perceived Stress (<i>Outcome Measure</i>)	Perceived Stress Scale	At baseline and at study completion, by participant
Perceived Self-Efficacy (<i>Outcome Measure</i>)	Geriatric Self-Efficacy Index of Urinary Incontinence	At baseline and at study completion, by participant
Rate and Trajectory of Change (<i>Process Measure</i>)	Patient Global Impression of Improvement (PGI-I)	After each session of treatment and comparison condition, by participant

7.6.2 Characteristics of Demographic Variables

Table 7 Characteristics of Overall Sample for Continuous Items ($N = 25$)

Characteristic	<i>M</i>	<i>SD</i>	Min-Max
Age (years)	73.52	8.45	56-87
BMI	28.33	8.88	18.37-61.08
Number of deliveries	3.44	2.55	0-12
Age of onset of menopause (years)	50.67	6.64	40-65
Length of urge incontinence symptoms (years)	7.97	9.81	3-50
Number of prescription medications	3.36	2.01	1-8
Daily caffeine use (serving)	1.33	1.44	0-4
Types of physical health conditions reported	.61	.94	0-3
Types of mental health conditions reported	.09	.29	0-1
Types of medications reported	.60	.65	0-2

Note. Missing responses were noted for items: Age of onset of menopause ($n = 3$), number of prescription medications ($n = 3$), daily caffeine use ($n = 1$), physical health conditions ($n = 2$), and mental health conditions ($n = 2$). Age of onset of menopause had 1 excluded response due to misunderstanding of the question.

Table 8 Characteristics of Overall Sample for Categorical Items ($N = 25$)

Characteristic	<i>n</i>	%
Marital Status		
Married	12	48.00
Other	13	52.00
Ethnicity		
Hispanic	3	12.00
Non-Hispanic	22	88.00
Highest Educational Attainment		
High school/GED or lower	3	12.00
Some college	6	24.00
Trade/technical/vocational Training	1	4.00
Associate degree	2	8.00
Bachelor degree	8	32.00
Master degree	4	16.00
Doctorate degree	1	4.00
History of Pregnancy		
Yes	23	92.00
No	2	8.00
Life Satisfaction		
Yes	24	96.00
No	1	4.00
Life Stressors		
Yes	6	24.00
No	19	76.00
Current Medical Conditions		
High blood pressure	9	36.00
Diabetes	4	16.00
Cancer	2	8.00
Heart problems	2	8.00
Major depression	1	4.00
Anxiety disorder	1	4.00
Current Medication Use		
Antidepressants or anxiolytics	7	28.00
Sleep medications	3	12.00
Pain medications	3	12.00
Beta-blockers	2	8.00

Note. Missing responses were noted for diabetes ($n = 1$), cancer ($n = 2$), heart problems ($n = 2$), major depression ($n = 2$), and anxiety disorder ($n = 2$)

7.6.3 Differences in Baseline Characteristics between MBSR and

HEP Conditions

Table 9 Fisher's Exact Test to Examine Differences in Categorical Baseline

Characteristics Between MBSR and HEP Conditions ($n = 13$; $n = 12$)

Baseline Characteristics	MBSR	HEP	<i>p</i> -value
	<i>n</i> (%)	<i>n</i> (%)	
Marital Status			.43
Married	5 (38.50)	7 (58.30)	
Other	8 (61.50)	5 (41.70)	
Race			1.00
White	11 (84.60)	10 (84.60)	
Non-White	2 (15.40)	2 (16.7)	
Ethnicity			.22
Hispanic	3 (23.10)	0 (0.00)	
Non-Hispanic	10 (76.90)	12 (100.00)	
Highest Educational Level			.01
Less than bachelor degree	10 (76.90)	2 (16.70)	
Bachelor degree or higher	3 (23.10)	10 (83.30)	
History of Pregnancy			1.00
Yes	12 (92.3)	11 (91.70)	
No	1 (7.70)	1 (8.30)	
Life Satisfaction			.48
Yes	13 (100.00)	11 (91.70)	
No	0 (0.00)	1 (8.30)	
Life Stressors			.38
Yes	2 (15.40)	4 (33.30)	
No	11 (84.60)	8 (66.70)	

Note. Bolded values indicate significance at $p < 0.05$.

Table 10 Mann-Whitney *U* Tests to Test for Differences in Baseline CharacteristicsBetween MBSR Versus HEP Conditions ($n = 13$; $n = 12$)

Baseline Characteristics	MBSR	HEP	Test Statistic	Standardized Test Statistic	<i>p</i> value
	<i>M (SD)</i>	<i>M (SD)</i>	<i>U</i>	<i>z</i> value	
Age (years)	73.92 (7.22)	73.08 (9.93)	76.00	-.11	.91
BMI	25.58 (4.57)	31.31 (11.43)	52	-1.41	.16
Number of deliveries	3.46 (3.05)	3.42 (2.02)	70.50	-.41	.68
Age of onset of menopause (years)	52.42 (7.79)	48.33 (4.00)	36.00	-1.28	.20
Length of urge incontinence symptoms (years)	9.56 (13.16)	6.25 (3.84)	76.00	-.11	.91
Number of prescription medications	3.09 (2.26)	3.64 (1.80)	46.50	-.93	.35
Daily caffeine use (serving)	1.17 (1.27)	1.50 (1.62)	65.50	-.39	.70
Types of physical health conditions reported	.38 (.65)	.90 (1.20)	50.00	-1.07	.29
Types of mental health conditions reported	.08 (.28)	.10 (.32)	63.50	-1.19	.85
Types of medications reported	.62 (.65)	.58 (.67)	75.50	-1.52	.88

7.6.4 Assumptions of Normality Associated with Outcome Measures

Table 11 Analysis of the Assumptions of Normality on Outcome Measures

Outcome measures	Normality	
	Yes	No
Incontinence Severity Index (ISI)	Q-Q plot, Kolmogorov-Smirnov (K-S), skewness coefficient, kurtosis coefficient	histogram, Shapiro-Wilk (S-W)
Overactive Bladder questionnaire (OAB-q)*	histogram, kurtosis, K-S, S-W g1, Q-Q g1	skewness, S-W g 2, Q-Q g2
Perceived Stress Scale (PSS)	skewness, kurtosis, histogram g2, K-S, S-W g2	histogram g1, K-S, S-W g1, Q-Q
Geriatric Self-Efficacy Urinary Incontinence (GSE-UI)	skewness, kurtosis, K-S, S-W g2, Q-Q g2	histogram, S-W g1, Q-Q g1

*Kolmogorov-Smirnov tests for OAB-q Part 1 ($p = .06$) and Part 2 ($p = .06$) assumed normality

7.6.5 Overall Intervention Results of Outcome Measures

Table 12 Analysis of the Effect of MBSR Versus HEP on Outcome Measures

Outcome Measure	Paired <i>t</i> test (<i>df</i> = 23)	<i>p</i> value	Wilcoxon Signed Ranks	<i>p</i> value
	Test Statistic (<i>t</i>)		<i>Z</i>	
ISI	4.32	.000	-3.27	.001
OAB-q complete (bother)	5.55	.000	-3.97	.000
OAB-q Part 1 (informal severity)	-.78	.222	-.015	.494
OAB-q part 2 (bother)	-5.44	.000	-3.94	.000
PSS	2.34	.014	-2.03	.021
GSE-UI	-2.26	.016	-1.99	.023

Note. Bolded values indicate significance at $p < 0.05$.

7.6.6 Within Group Results using Paired t Tests and Wilcoxon Signed Ranks Test

Table 13 Within Group Results Using Paired t tests and Wilcoxon Signed Ranks Test (MBSR condition)

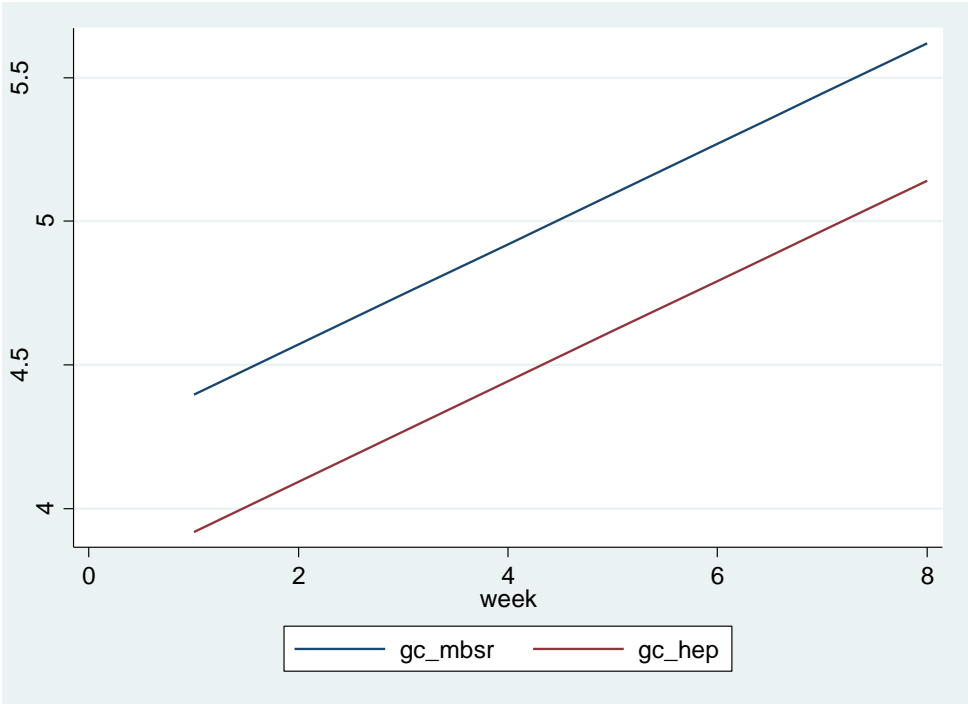
Outcome Measure	MBSR		Paired t test			Wilcoxon Signed Ranks Test	
	Pretest M ($n = 12$)	Posttest M ($n = 12$)	T	df	p	Z	p
ISI	7.00	4.08	2.80	11	.009	-2.23	.011
OAB-q	64.25	38.83	5.12	11	.000	-3.06	.001
PSS	11.00	7.92	1.96	11	.038	-1.078	.140
GSE-UI	71.83	88.33	-2.60	11	.013	-2.35	.010

Table 14 Within Group Results Using Paired t tests and Wilcoxon Signed Ranks Test (HEP condition)

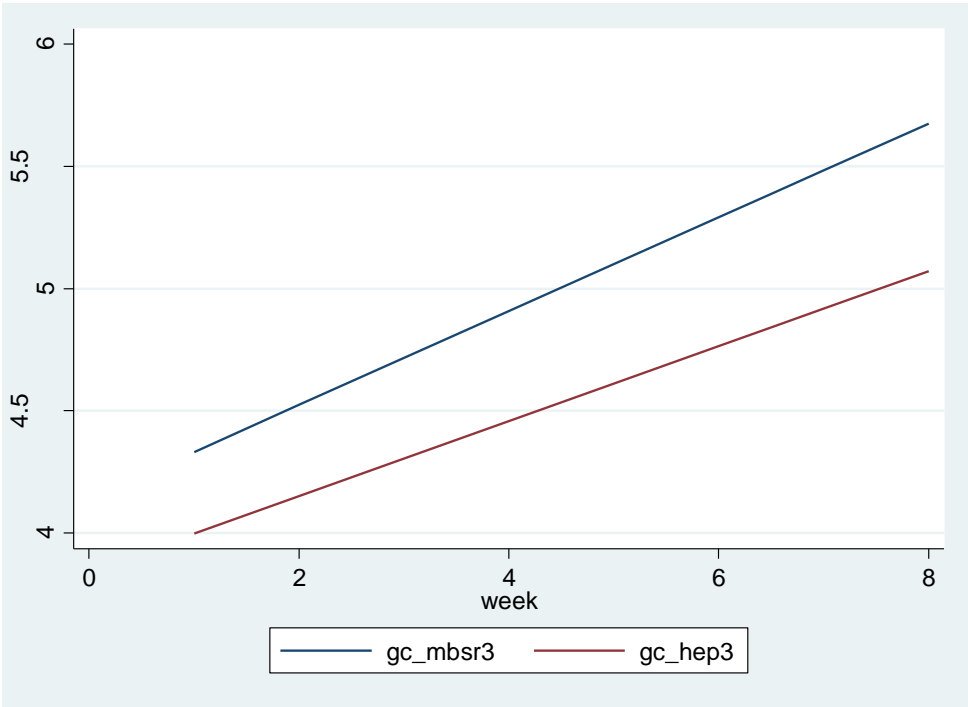
Outcome Measure	HEP		Paired t test			Wilcoxon Signed Ranks Test	
	Pretest M ($n = 12$)	Posttest M ($n = 12$)	T	df	p	Z	p
ISI	9.00	6.08	3.21	11	.004	-2.44	.008
OAB-q	69.33	50.92	2.97	11	.007	-.258	.005
PSS	13.58	11.67	1.28	11	.113	-1.42	.079
GSE-UI	59.83	65.92	-.793	11	.222	-.510	.305

Note. Bolded values indicate significance at $p < 0.05$.

7.6.7 Patient Global Impression of Improvement



Model 2



Model 3

Figure 4 Process Measure Results, Graphed

7.6.8 Between Group Results Using Independent Samples *t* Tests and Mann Whitney *U* Tests and Effect Size on Outcome

Measures using Parametric and Nonparametric Tests

Table 15 Effect Size and Power Analysis of Differences in Outcome Measures Between MBSR and HEP

Using Independent Samples <i>t</i> test							
Outcome Measures	MBSR		HEP		Independent Samples <i>t</i> tests	Effect Size	Power Analysis
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>P</i>	Cohen's <i>d</i>	
Incontinence Severity Index (ISI)	4.08	3.45	6.08	3.45	.07	.579	.27
Overactive Bladder questionnaire (OAB-q)	38.83	17.73	50.92	20.21	.07	.64	.32
OAB-q Part 1	-	-	-	-	.08	-	-
OAB-q Part 2	-	-	-	-	.08	-	-
Perceived Stress Scale (PSS)	7.92	7.29	11.67	8.72	.14	.47	.20
Geriatric Self-Efficacy Urinary Incontinence (GSE-UI)	88.33	36.37	65.92	31.43	.06	.66	.34

Table 16 Effect Sizes and Power Analysis of Differences in Outcome Measures Between MBSR and HEP Using

Mann-Whitney U Tests

Outcome Measures	Test Statistic	Standardized Test Statistic	Sig. 1-tailed	Effect Size
	U	Z value	p value	r
ISI	46.5	-1.493	.07	.32 low
OAB-q	105.000	1.907	.06	.73 strong
OAB-q (part 1)	38.50	-1.94	.03	-
OAB-q (part 2)	38.50	-1.94	.03	-
PSS	49.5	-1.301	.10	.34 low
GSE-UI	45	-1.560	.06	.31 low

Note. Bolded values indicate significance at $p < 0.05$.

CHAPTER 8

DISCUSSION

The findings of this study support the feasibility of conducting a randomized controlled trial of complementary therapies to treat UUI in older women, as well as demonstrating short-term preliminary efficacy of these modalities. All goals and benchmarks of the two feasibility aims were achieved, despite the challenges of executing a clinical trial among older adult women with a sensitive chronic condition. Both the research feasibility aims of recruitment, retention, and the five categories of treatment fidelity (fidelity in study design, provider training, enactment of treatment skills, and treatment receipt) as well as the intervention feasibility aims—acceptability, tolerability, and treatment adherence were accomplished. This encouraging outcome suggests that while women and older adults remain underrepresented in scientific research, the recruitment and enrollment of older adult women with a sensitive condition into a clinical trial is both a worthy and attainable endeavor. Despite the organization of large national research centers, this underrepresentation in clinical trials, and subsequently in the literature, persists ("Barriers to women's participation in clinical trials and SWHR proposed solutions,"; Herrera et al., 2010; Mody et al., 2008; Provencher, Mortenson, Tanguay-Garneau, Belanger, & Dagenais, 2014). As such, this study has value simply from the examination of the older adult woman as research participant.

The PI posited that the MBSR arm of the intervention would have superior impact on outcome and process measures, including reduced severity, bother, and perceived stress, and increase of self-efficacy surrounding urinary incontinence, as well as the rate and trajectory of perceived improvement. The short-term preliminary efficacy analysis showed MBSR superior to HEP in reducing severity and bother with *p* values of .05 on both measures. However, these significant results were only seen when analyzing the

Overactive Bladder Questionnaire Short Form in its two parts, not overall. The preliminary efficacy analysis of the process measure, PGI-I, also showed statistical significance between MBSR and HEP. A trend was also observed that MBSR may achieve improvement faster than HEP, although, due to the smaller sample, statistical significance was not observed.

The preliminary efficacy analysis did not support MBSR as superior to HEP in reducing severity or bother using the ISI, the validated full OAB-q, or in reducing perceived stress (measured by the PSS), or in increasing efficacy measured with the GSE-UI when analyzing significance using *p* values. However, the effect sizes were moderate, with Cohen's *d* values ranging from .47-.66. The findings, although not statistically significant, were notable, as each condition evaluated separately evidenced statistically significantly improvement in severity, bother, perceived self-efficacy, and perceived improvement. When analyzed as a total sample ($N = 24$), all outcome and process measures were statistically significant. This indicates that older adult women with urge urinary incontinence may improve using both of these treatment conditions.

Lack of statistical significance, given the more robust effect sizes, is most likely due to small sample size, as is congruent with pilot study work. This is further verified when examining the PGI-I data, which, having more data points, yielded statistical significance and a truer picture of the difference between MBSR and HEP.

Another main reason may be the study design of comparing two approaches that have a likelihood of working, rather than comparing one intervention with nothing. The chosen study design is responsive to the NIH's 2008 call to provide an active comparison condition to MBSR studies that is of equivalent commitment and experience (Ospina et

al., 2008). The fact that MBSR was not statistically superior to HEP in this stage of research says as much about the value of HEP as the potential superiority of MBSR.

Perhaps the most compelling finding in the study was that both MBSR and HEP reduced urinary incontinence symptoms in older adult women, suggesting that a combination of MBSR and HEP treatment elements may be yet more efficacious. A combination of therapies including MBSR and empirically derived elements of HEP may produce greater therapeutic change and will be the basis of further research to treat this complex condition whose highest prevalence occurs in the older adult female population.

An impressive level of engagement was consistently seen in both subsamples. Treatment adherence was measured through attendance and homework completion. Typical adherence to treatment regimen rates in adults are 60-75% (DiMatteo, 2004a, 2004b; Dunbar-Jacob & Schlenk, 2001). Attendance for the MBSR condition averaged 95.96% and attendance for the HEP condition averaged 97.22%. Homework submission for the MBSR condition averaged 88.43%. Homework submission for the HEP condition averaged 89.57%. This is evidence of a desire to address a sensitive condition in this population as well as an underappreciated willingness of older adults to participate in clinical health care research. Even participants who stopped attending either MBSR or HEP courses returned for data collection at completion. In a second example, the entire HEP class willingly adapted to a different meeting day to accommodate an interventionist's schedule.

8.1 Implications

The next phase of this study specifies a 6-month follow-up, which was explained in consent and enrollment, and a reminder was given at intervention completion. Each participant, including those who withdrew from the course, will be invited to fill out the five measurements once more: the ISI measuring severity, the OAB-q measuring bother, the PSS measuring perceived stress, the GSE-UI measuring urinary incontinence self-efficacy, and the PGI-I measuring trajectory of change. This phase also includes a recorded interview of open-ended questions to examine the phenomenological experience of the participants. This qualitative information will be supplemented by qualitative information gathered from participants when expressing their feedback regarding acceptability.

These study findings support the merit of future research in larger scale and/or multisite trials. Future research will include a larger scale effectiveness trial. One of the successes of this study was to recruit older women. Given that momentum, the effectiveness study would also seek to include women of more diverse racial and ethnic heritage and a broader geographic distribution. Knowing that it is feasible to recruit women 65 and older, future studies would confine eligibility to age 65+, rather than postmenopausal status. Findings from this larger fully powered effectiveness study could also yield better instrumentation, specifically in the measurement of urge severity.

In addition, development and evaluation of a combined MBSR and HEP therapy to address UUI in older adult women is hypothesized to produce higher efficacy across study domains, and merits further study. A subsequent analysis would be to combine MBSR treatment with evidence-based components of HEP. Combined use of MBSR and

identified HEP treatment elements has potential application to other chronic conditions associated with aging, blood pressure regulation, early stage cognitive impairment, and mobility risks such as dizziness, syncope, and falls.

8.2 Conclusion

This feasibility study and randomized controlled preliminary efficacy trial have been described from design to final analysis. Information regarding prior scientific literature, theories influencing design, study rationale, and aims with research questions has been comprehensively provided. Additionally, trial design, sample size, eligibility criteria, study locations, intervention descriptions, measures, and data analysis with concordant results have been clearly outlined, congruent with CONSORT and SPIRIT standards for responsible research conduct and reporting.

This study demonstrated the successful feasibility of conducting a study using nonsurgical, nonpharmacological, mind–body and educational therapies to treat urge urinary incontinence in older adult women, including women in their late 80s. This RCT also demonstrated short-term preliminary efficacy to various degrees in reduction of severity, bother, perceived stress and increase in perceived self-efficacy and perceived improvement. While the sample size was modest, as is consistent with pilot studies, it was a sufficient size to randomize participants into two treatment conditions, in which each treatment condition would provide a therapeutically appropriate size for each intervention design. The RCT structure provided rigor and reduced threats to validity.

This study supports prior research suggesting potential efficacy of MBSR in

treating UUI in older adult women. Study findings contribute to our understanding of the complex condition of UUI in an older, more vulnerable, and underrepresented population.

8.3 References

- Barriers to women's participation in clinical trials and SWHR proposed solutions.
Retrieved from <https://swhr.org/barriers-to-womens-participation-in-clinical-trials-and-swahr-proposed-solutions/>
- DiMatteo, M. R. (2004a). Social support and patient adherence to medical treatment: A meta-analysis. *Health Psychology, 23*(2), 207-218. doi:10.1037/0278-6133.23.2.207
- DiMatteo, M. R. (2004b). Variations in patients' adherence to medical recommendations: a quantitative review of 50 years of research. *Medical Care, 42*(3), 200-209.
- Dunbar-Jacob, J., & Schlenk, E. (2001). Patient adherence to treatment regimen. In A. Baum, T. A. Revenson, & J. E. Singler (Eds.), *Handbook of health psychology* (pp. 571–580). Mahwah, NJ: Erlbaum.
- Herrera, A. P., Snipes, S. A., King, D. W., Torres-Vigil, I., Goldberg, D. S., & Weinberg, A. D. (2010). Disparate inclusion of older adults in clinical trials: Priorities and opportunities for policy and practice change. *American Journal of Public Health, 100*(suppl 1), 105-112. doi:<http://doi.org/10.2105/AJPH.2009.162982>
- Mody, L., Miller, D. K., McGloin, J. M., Freeman, M., Marcantonio, E. R., Magaziner, J., & Studenski, S. (2008). Recruitment and retention of older adults in aging research. *Journal of the American Geriatric Society, 56*(12), 2340-2348. doi:10.1111/j.1532-5415.2008.02015.x
- Ospina, M. B., Bond, K., Karkhaneh, M., Buscemi, N., Dryden, D. M., Barnes, V., . . . Shannahoff-Khalsa, D. (2008). Clinical trials of meditation practices in health care: characteristics and quality. *Journal of Alternate Complementary Medicine, 14*(10), 1199-1213. doi:10.1089/acm.2008.0307
- Provencher, V., Mortenson, W. B., Tanguay-Garneau, L., Belanger, K., & Dagenais, M. (2014). Challenges and strategies pertaining to recruitment and retention of frail elderly in research studies: A systematic review. *Archives of Gerontology and Geriatrics, 59*(1), 18-24. doi:10.1016/j.archger.2014.03.006